



63 Zillicoa Street
Asheville, NC 28801
© Genova Diagnostics

Patient: **SAMPLE
PATIENT**

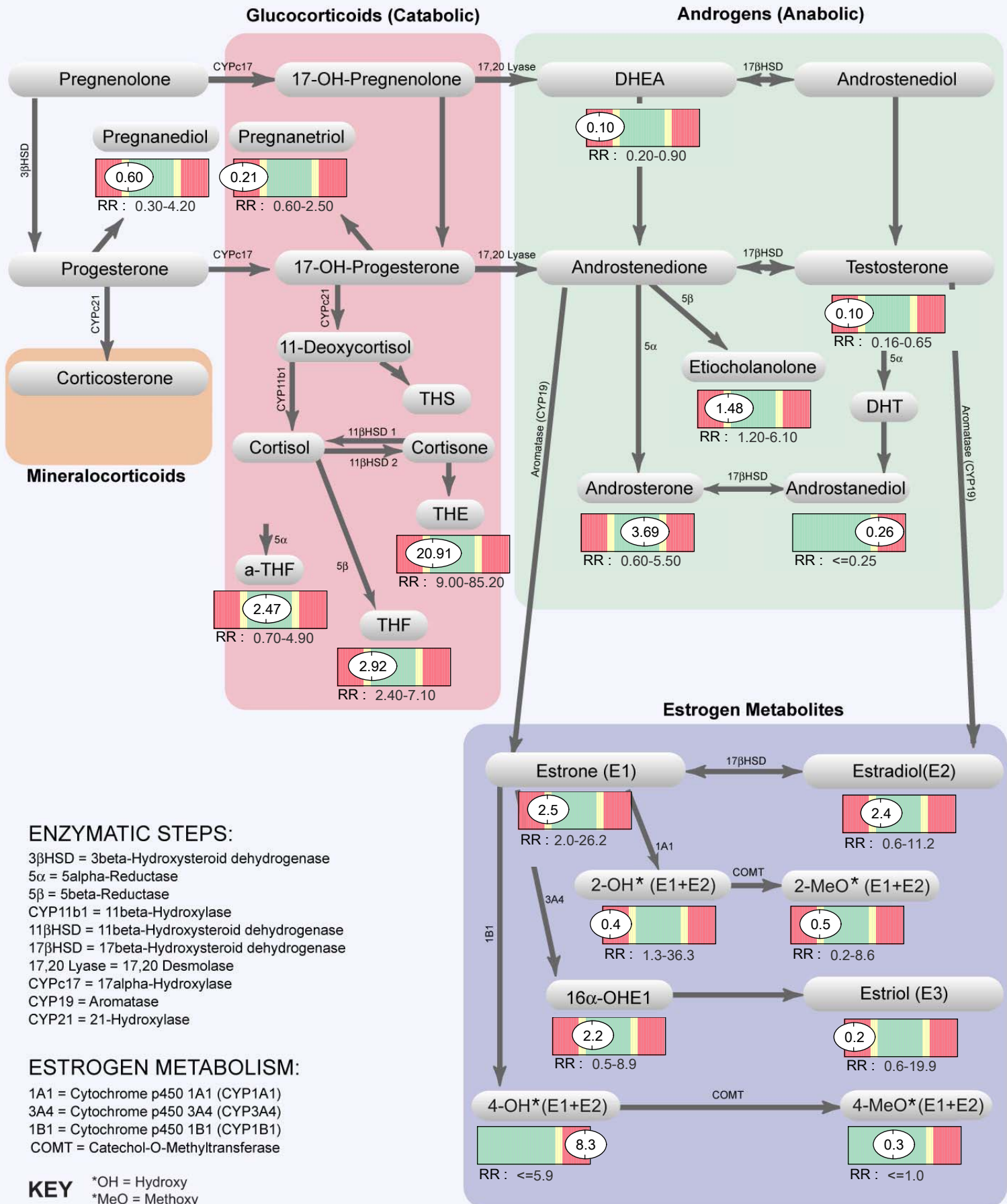
DOB:

Sex:

MRN:



Steroidogenic Pathway At-A-Glance



Interpretation At-A-Glance

Anabolic/Catabolic Balance 17-Ketosteroids/17-Hydroxysteroids Ratio



Catabolic

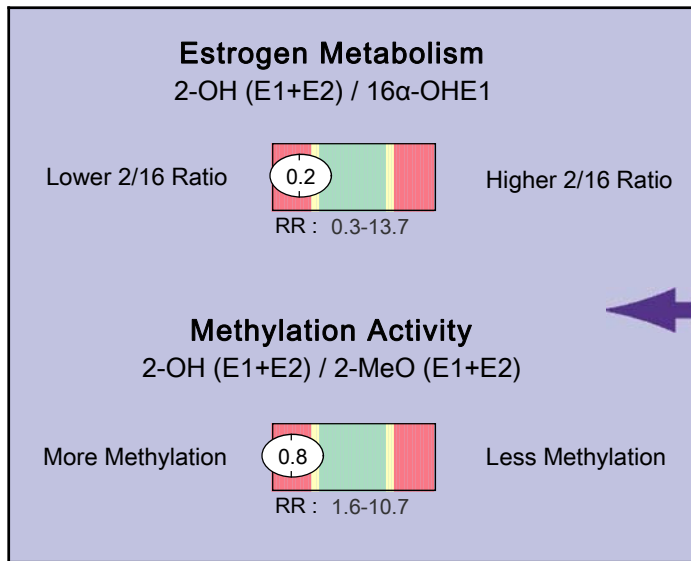


Anabolic



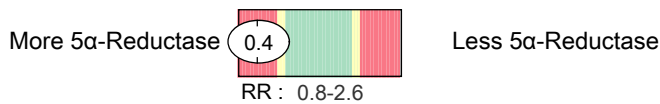
* Total values equal the sum of all measurable parts

Enzymatic Activity

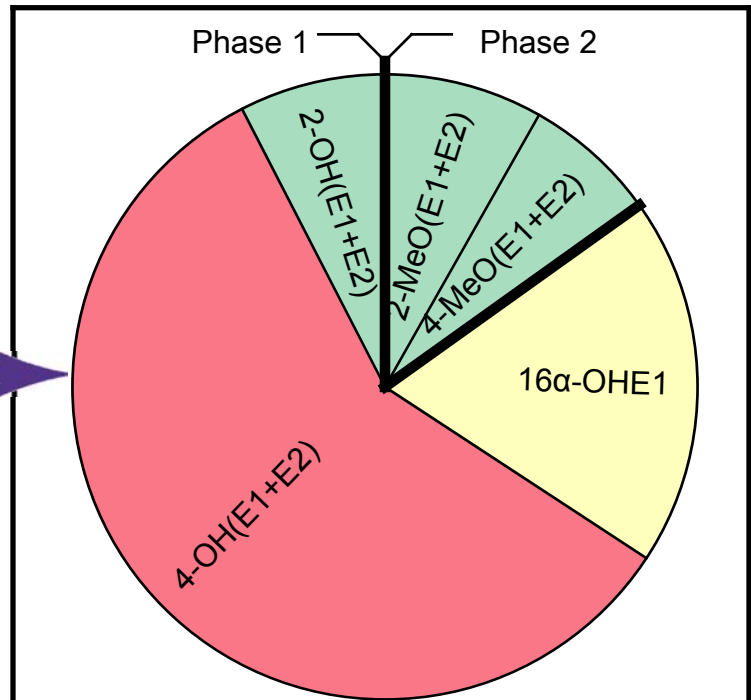


5 α -Reductase Activity

Etiocholanolone/Androsterone (E/A) Ratio

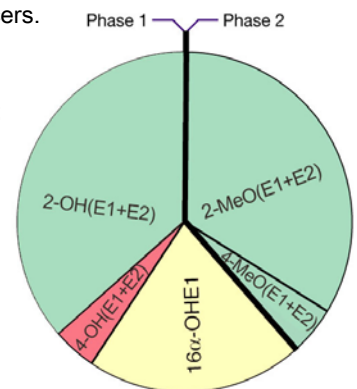


Estrogen Metabolism



This sample pie-chart reflects current scientific understanding of the association of specific estrogen metabolites with disease risk for hormone related cancers.

Metabolites in green have been associated in the literature with decreased risk; those in red, with increased risk. 16-OHE1 (in yellow) has mixed findings, some studies showing an association and many finding no association. The dark line separates Phase 1 and Phase 2 detoxification pathways.



Key

Complete Hormones (24hr)



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Asheville, NC 28801
© Genova Diagnostics

Patient: **SAMPLE
PATIENT**

DOB:

Sex:

MRN:

Methodology: GC-MS and LC-MS/MS; Specimen: 24 hour urine; Results normalized to volume

Progesterone

		Reference Range
Pregnanediol (24hr urine)	0.60	0.30-4.20 micromol/24 hr

Androgens

17-Ketosteroids

		Reference Range
DHEA (24hr urine)	0.10	0.20-0.90 micromol/24 hr
Androsterone (24hr urine)	3.69	0.60-5.50 micromol/24 hr
Etiocholanolone (24hr urine)	1.48	1.20-6.10 micromol/24 hr
11-Keto-androsterone (24hr urine)	0.20	0.30-1.90 micromol/24 hr
11-Keto-etiocholanolone (24hr urine)	0.34	0.30-1.60 micromol/24 hr
11-Hydroxy-androsterone (24hr urine)	3.17	1.30-4.10 micromol/24 hr
11-Hydroxy-etiocholanolone (24hr urine)	0.31	0.50-2.60 micromol/24 hr
17-Ketosteroids, Total* (24hr urine)	9.3	6.0-22.2 micromol/24 hr

* Total values equal the sum of all measurable parts

Testosterone (24hr urine)	0.10	0.16-0.65 micromol/24 hr
Androstanediol (24hr urine)	0.26	<= 0.25 micromol/24 hr

Glucocorticoids

17-Hydroxysteroids

		Reference Range
Pregnanetriol (24hr urine)	0.21	0.60-2.50 micromol/24 hr
allo-Tetrahydrocortisol, a-THF (24hr urine)	2.47	0.70-4.90 micromol/24 hr
Tetrahydrodeoxycortisol, THS (24hr urine)	0.17	<= 1.00 micromol/24 hr
Tetrahydrocortisone, THE (24hr urine)	20.91	9.00-85.20 micromol/24 hr
Tetrahydrocortisol, THF (24hr urine)	2.92	2.40-7.10 micromol/24 hr
17-Hydroxysteroids, Total* (24hr urine)	26.7	14.0-105.2 micromol/24 hr

* Total values equal the sum of all measurable parts

Estrogens

Estrogens

Reference Range

Estrone (E1)*	2.5	2.0-26.2 mcg/g Creat.
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	2.0-26.2 mcg/g Creat.
Menopause	1.1-26.2 mcg/g Creat.
Male	1.6-8.6 mcg/g Creat.

Estradiol (E2)*	2.4	0.6-11.2 mcg/g Creat.
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	0.6-11.2 mcg/g Creat.
Menopause	0.6-15.4 mcg/g Creat.
Male	0.8-4.3 mcg/g Creat.

Estriol (E3)*	0.2	0.6-19.9 mcg/g Creat.
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	0.6-19.9 mcg/g Creat.
Menopause	0.7-30.8 mcg/g Creat.
Male	0.3-5.1 mcg/g Creat.

Estrogen Metabolites

2-Hydroxyestrone + 2-Hydroxyestradiol [2-OH(E1+E2)]*	0.4	1.3-36.3 mcg/g Creat.
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	1.3-36.3 mcg/g Creat.
Menopause	0.9-43.8 mcg/g Creat.
Male	0.7-12.5 mcg/g Creat.

16 α -Hydroxyestrone (16 α -OH E1)*	2.2	0.5-8.9 mcg/g Creat.
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	0.5-8.9 mcg/g Creat.
Menopause	0.4-7.7 mcg/g Creat.
Male	<=2.0 mcg/g Creat.

4-Hydroxyestrone+4-Hydroxyestradiol [4-OH(E1+E2)]*	8.3	<= 5.9 mcg/g Creat.
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	<=5.9 mcg/g Creat.
Menopause	<=8.8 mcg/g Creat.
Male	<=1.6 mcg/g Creat.

2-Methoxyestrone+2-Methoxyestradiol [2MeO(E1+E2)]*	0.5	0.2-8.6 mcg/g Creat.
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	0.2-8.6 mcg/g Creat.
Menopause	0.3-5.9 mcg/g Creat.
Male	0.2-2.5 mcg/g Creat.

4-Methoxyestrone+4-Methoxyestradiol [4MeO(E1+E2)]*	0.3	<= 1.0 mcg/g Creat.
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	<=1.0 mcg/g Creat.
Menopause	<=1.0 mcg/g Creat.
Male	<=1.0 mcg/g Creat.

Estrogens

Ratios

Reference Range

Anabolic/Catabolic Balance (24hr urine)	0.3	0.1-1.5
E/A: 5β/5α Ratio (24hr urine)	0.4	0.8-2.6
2-OH(E1+E2) / 16α-OHE1*	0.2	0.3-13.7

* Premenopause(luteal) reference range shown

Reference Ranges	
Premenopause	0.3-13.7
Menopause	0.3-15.1
Male	0.8-12.9

2-OH(E1+E2) / 2-MeO(E1+E2)*	0.8	1.6-10.7
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* Premenopause (luteal) reference range shown

Reference Ranges	
Premenopause	1.6-10.7
Menopause	0.4-11.6
Male	1.0-8.8

Lab Comments

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.

Please note the reference range for Tetrahydrocortisone (THE), Total 17-OH Corticosteroids, and the Anabolic/Catabolic Balance have been updated.

Please note analysis of estrogens and estrogen metabolites is now performed using LC/MS/MS. The reference ranges for these biomarkers have been updated.

WHEN READY TO SHIP, ENSURE THE FOLLOWING:

Cup:

- Tightly closed
- Marked with **first and last name, date of birth, and date and time of collection.**
- Sealed in biohazard bag with absorbent pad

Swabs:

- Included- inside original package
 - Marked with **first and last name, and date of collection.**
- All sections of **requisition form completed.**
- Payment included** or completed online.
- All specimens** placed back in original box.
- Complete survey**

SHIP THE SPECIMEN(S) TO THE LAB

Please refer to the shipping instruction insert found in your sample collection pack.

VISIT YOUR PATIENT RESOURCE CENTER AT WWW.GDX.NET/PRC

- Access test results
- Make payments
- Complete health surveys



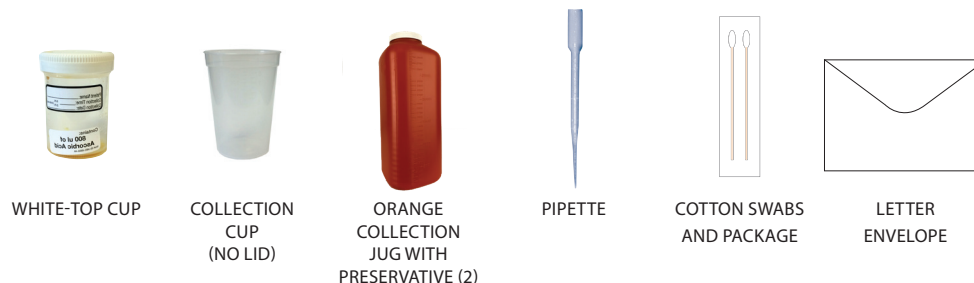
Call **800.522.4762** or visit our website at www.gdx.net

URINARY HORMONES ENDOCRINOLOGY

PATIENT 24-HOUR URINE & BUCCAL SWAB COLLECTION INSTRUCTIONS FOR THE FOLLOWING PROFILE(S)

Complete Hormones™ *	Urine	#4200
Essential Estrogens™ *	Urine	#4209
Genomics a-la-carte SNPS*	Buccal Swab	

COLLECTION MATERIALS FOR SPECIMEN



• **CAUTION: Contains Absorbic Acid. KEEP OUT OF REACH OF CHILDREN.**

For eye contact, flush with water for 15 mins. For skin contact, wash with soap and water. For ingestion, contact poison control center immediately.

ADDITIONAL MATERIALS

- Disposable vinyl gloves (2)
- Collection labels
- Test Questionnaire
- Test requisition form
- Biohazard bag with side pocket with absorbent pad
- Specimen collection pack
- FedEx® Clinical Lab Pak and Billable Stamp

If any items are missing or expired, or liquid is spilled, call Client Services at 800.522.4762 and press "1"

IMPORTANT PREP BEFORE PATIENT TAKES TEST

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

- Synthetic hormones will not show up on the test and conjugated equine estrogens will show up mostly as estrone.
- Abnormal kidney function or use of diuretics may influence test results. Do not perform on individuals with kidney disorders.
- Certain medicines may impact test results (e.g. cephalosporins, cimetidine, fibrates and trimethoprim-sulfamethoxazole). Let your physician know about your use of these medications. Do not change use of medications unless instructed to do so by your healthcare provider.
- Premenopausal women: If the goal is to evaluate ovulatory function, collect urine between days 19-25 of the menstrual cycle.
- Menopausal women: Collect specimen on any day.
- Women on Hormone Replacement Therapies or oral contraceptives: Continue dosing as usual.
- Follow-up testing: Collect the specimen on the same day of cycle or phase of hormone therapy as the previous sample.
- CAUTION: Do not discard white powder contained in the jugs.

* Not available in New York

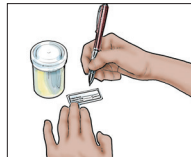


48 HOURS BEFORE THE TEST: Avoid eating (whole or ground) flax seeds and sesame seeds for at least 48 hours before urine collection begins.

Delay collection if you have a urinary tract infection until after completing treatment.

DAY BEFORE THE TEST: Avoid over hydration. Aim for average overall fluid intake of 1/2 oz water/fluid per pound of body weight per day. Example: 130 lbs -65 oz. (eight 8 oz. glasses)

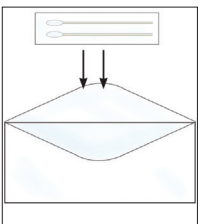
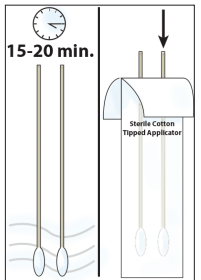
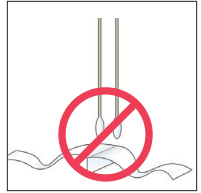
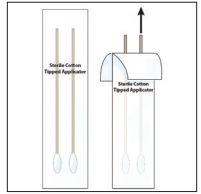
- 1 Completely **fill out** front and back of test requisition form. Failure to provide all information will result in delay of test processing.
- 2 Please **write the patient's full name, the time and date of collection, and date of birth** on the label and apply it to the white-top cup.
- 3 **Put** on glove. Hold the large orange jug to avoid spilling the white powder.
- 4 On first day, **discard** the first urination after rising. **Collect** all urinations for the next 24 hours, including your first urination after rising the next day.
- 5 **Collect** each urination in the disposable cup and pour into the large orange jug. **Do not rinse** or clean the cup. **Recap** jug and **mix gently**. **Refrigerate** jug through 24 hour collection period.
- 6 **IF YOU ONLY FILL ONE JUG, screw** the lid on tightly. **Set** on a level surface and **note** the total volume using the milliliters (ml) marks on the side of the jug. **Be sure to record this on the requisition form**. Lab processing cannot be completed without this information. Gently **mix** for 30 seconds. Skip to step #7.
- 7 **IF YOU FILL TWO JUGS, put** on the disposable gloves and **mix** the urine together by **pouring back and forth** between the jugs. **Do not spill** urine. **Set** jugs on a level surface and note the volumes using the milliliter marks on the side of the jugs. **Add together the amount in jug #1 and the amount in jug #2. Be sure to record this on the requisition form**. Lab processing cannot be completed without this information.
- 8 **Pour** urine from Jug #1 into the white-top cup to **between 100 ml and 120 ml mark**. **Screw** the top on the cup tightly to avoid leakage. **Discard** the remaining urine, the large collection jug(s), pipette, and gloves.
- 9 **Place** the cup in the Biohazard bag. **Refrigerate** until ready to ship. Remember to ship within 48 hours after final collection.



NIGHT BEFORE COLLECTION: Use your normal nightly routine of brushing and flossing of teeth but do not use mouthwash.

MORNING OF COLLECTION: Specimen must be **collected immediately** upon rising. Do not practice normal oral hygiene routine, **do not eat or drink ANYTHING OTHER THAN WATER**.

- 1 Just prior to collection, **wash hands** completely with hand soap.
 - 2 **Keeping the packet intact, peel open** the package labeled, "Sterile Cotton Tipped Applicator."
 - 3 **Only peel back the package far enough to remove the cotton swab applicator.**
 - 4 **Remove** one applicator. **Avoid contact** with the cotton tip.
 - 5 **Open** your mouth widely and insert applicator. **For at least 30 seconds, aggressively scrape** the inside of both cheeks using a back and forth, and up and down motion. **Rotate** the applicator several times, and **swab** between the cheek and gums. **Avoid** excessive saliva.
- Note: If there is not a sufficient amount of cheek cells DNA collected on the applicator, a recollection will be required.*
- 6 **REPEAT STEPS 1 - 5 WITH SECOND SWAB**
 - 7 **Allow swabs to air dry for 15-20 minutes**, then **replace** them (swab first) into the swab applicator package.
 - 8 **Print Full name and collection date on specimen collection label.** Place the specimen collection label on the envelope.
 - 9 **Insert** swab applicator package into the letter envelope and seal. **Be sure to ship with urine sample.**



CHECKLIST (PRIOR TO SHIPPING)

1. White-top cup

LABEL

- Patient's first/last name
- Date of birth
- Date of collection
- The specimen does not exceed the FILL LINES
- Cup is tightly closed
- Refrigerated

2. Envelope with buccal swabs (if collecting for Genomic add-ons)

LABEL

- Patient's First/Last Name
- Date of Collection

3. Test Requisition Form with payment

- Test Requisition Form is complete

LABEL:

- Patient's first/last name
- Date of birth
- Gender
- Date of collection
- Total urine volume
- Payment is included

SHIP THE SPECIMEN TO THE LAB

Specimen(s) must be returned in the Genova Diagnostics kit box.

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

URINE, FIRST MORNING VOID (FMV) COLLECTION INSTRUCTIONS #75 PATIENT URINE & BUCCAL SWAB COLLECTION INSTRUCTIONS

URINARY HORMONES ENDOCRINOLOGY

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

Complete Hormones™ Essential Estrogens™

Add-ons available

- Triiodothyronine, T3
- Cortisol, Free
- Genomics a-la-carte SNPs
 - › MTHFR
 - › COMT
 - › VDR
 - › CYP-1B1



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

White-top Cup



Please provide:

- Patient's Date of Birth

Specimen

120 ml sample of urine
Buccal Swab

(only for Genomics add-ons)

Shipping Materials

- Glove
- Biohazard bag with absorbent material
- Test Requisition Form
- Collection label
- Questionnaire
- Prepaid mailing envelope

Collection Materials for Urine



White-top cup



Collection cup
(no lid)

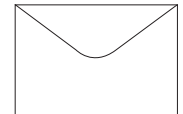


Pipette

Collection Materials for Buccal Swab



Cotton Swabs
and package



Letter envelope

IMPORTANT THINGS TO KNOW AND CONSIDER

- Synthetic hormones** will not show up on the test and conjugated equine estrogens will show up mostly as estrone.
- Abnormal kidney function** or use of diuretics may influence test results. Do not perform on individuals with kidney disorders.
- Certain medicines** may impact test results (e.g. cephalosporins, cimetidine, fibrates and trimethoprim-sulfamethoxazole). Let your physician know about your use of these medications. **Do not change** use of medications unless instructed to do so by your healthcare provider.



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

URINE COLLECTION

COLLECTION CRITERIA AND CAUTIONS

- ❑ **Premenopausal women:** If the goal is to evaluate ovulatory function, collect urine between *days 19-25* of the menstrual cycle.
- ❑ **Menopausal women:** Collect specimen on any day.
- ❑ **Women on hormone replacement therapies or oral contraceptives:** Continue dosing as usual.
- ❑ **Follow-up testing:** Collect the specimen on the same day of cycle or phase of hormone therapy as the previous sample.
- ❑ **Avoid contact** with the eyes or skin. For contact with eyes, wash for 15 minutes. For skin contact, wash thoroughly with soap

and water. Do not inhale or ingest liquid or powder.

48 HOURS BEFORE THE TEST:

48

- ❑ **Avoid** eating (whole or ground) flax seeds and sesame seeds for at least 48 hours before urine collection begins.

DAY BEFORE THE TEST:

24

- ❑ **Avoid** over hydration. Aim for average overall fluid intake of 1/2 oz water/fluid per pound of body weight per day. Example: 130 lbs -65 oz. (eight 8 oz. glasses).

Before collecting your specimen, refer to the shipping instructions to determine what day you can ship. Ship only Monday through Friday and **within 48 hours after final collection.**

- 1 IMPORTANT: To ensure accurate test results you MUST provide the requested information on the labels and the requisition. See checklist on back.**

- 2 If you wake up to urinate during the night** (within six hours of waking), **collect** with the provided collection cup, or a clean, disposable container, and refrigerate it.

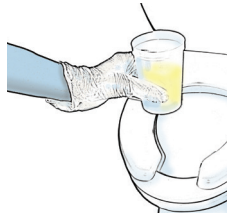
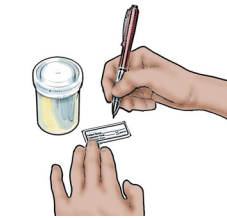
- 3** Upon waking **collect** your urine into the same cup/container. **Fill** the cup/container and, pass any additional urine into the toilet.

- 4** **Open** the white-top cup. **Pour** urine from the collection cup into the white-top cup to approximately the 100ml mark, and then **use** the pipette to reach the 120ml mark. **Screw** the white top on the cup tightly to avoid leakage and shake to mix thoroughly.

- 5** **Discard** the remaining urine, collection cup, pipette, and glove.

- 6** **Place** the white-top cup into the biohazard bag and **refrigerate** until ready to ship.

- 7** **Ship within 48 hours after collection.**



BUCCAL SWAB COLLECTION (ONLY FOR GENOMICS ADD-ON TESTING)

NIGHT BEFORE COLLECTION:



- ❑ Use your normal nightly routine of brushing and flossing of teeth, but do not use mouthwash.

MORNING OF COLLECTION:



- ❑ Specimen must be collected immediately upon rising. Do not practice normal oral hygiene routine, do not eat or drink **ANYTHING OTHER THAN WATER.**
- ❑ Just prior to collection, wash hands completely with hand soap.

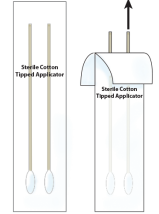
For full details refer to: www.gdx.net/tests/prep

- 1** **Keeping the packet intact, peel** open the package labeled, "Sterile Cotton Tipped Applicator." **Only peel back the package far enough to remove the cotton swab applicator.**



- 2** **Remove** one applicator. *Avoid contact with the cotton tip.*

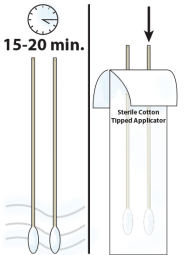
- 3** **Open** your mouth widely and insert applicator. For at least 30 seconds, **aggressively scrape** the inside of both cheeks using a back and forth, and up and down motion. **Rotate** the applicator several times, and **swab** between the cheek and gums. **Avoid** excessive saliva.



Note: Unless a sufficient amount of cheek cells DNA is collected, a recollection will be required.

REPEAT FIGURES 1 - 3 WITH SECOND SWAB

- 4** **Allow** swabs to air dry for 15-20 minutes, then replace them (swab first) into the swab applicator package.



- 5** **Print** Full name and collection date on specimen collection label. **Place** the specimen collection label on the envelope.

- 6** **Insert** swab applicator package into the letter envelope and seal. Be sure to ship with urine sample.

