

Diagnos-Techs™

Clinical & Research Laboratory
Quarterly Newsletter

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"Build Your Own Panel"

Chronobiology and Diagnos-Techs™ Test Panels



The title of your regular newsletter from Diagnos-Techs™ is "Chronobiology Letter". Central to this concept is the ability of Diagnos-Techs™ to not only provide accurate scientific

results for your patients but also provide these data over time in order to depict their variations and vagaries throughout a particular periodic cycle. This is easily accomplished due to the unique nature of saliva testing. Multiple, potentially traumatic venipunctures are avoided, and testing is completely private.

Continued on page 5



Director of Medical Support

John White, MD, CM

After more than five years as one of the medical consultants at Diagnos-Techs™, I have the distinct privilege to be appointed Director of Medical Support. In this role, I will continue to build upon our already outstanding department, to initiate updates and adjustments in our test instructions and reporting of results, and to be a channel for the comments of our clientele. In the latter regard, please call me at our general number, **800.878.3787** with your suggestions.

I received an MD, CM degree from McGill University, spent two years active duty with the US *Continued on page 6*

Diagnos-Techs™ Launches New Website

This summer you will see a new and improved face of Diagnos-Techs on the World Wide Web. Some exciting features include new provider locator, user friendly provider login page, UPS Returns on the Web, easy-to-access reports, and much more! Please check out the site at www.diagnostechs.com.



New Test Kit Boxes and Easy Shipping with UPS!

Diagnos-Techs™ announces new, larger test kit boxes and a partnership with UPS (United Parcel Service) enabling us to improve our overall shipping and provide our clients and their patients fast and convenient service, such as:

- ✓ One- to three-day service, depending on US location
- ✓ Pre-paid return shipping label with each kit box
- ✓ New, easy-to-follow instructions with each test kit
- ✓ Larger boxes with colorful design

Please see new detailed shipping instructions on page seven. Be sure to remind your patients to deliver their test kits to their most convenient UPS location. For more information, visit www.UPS.com/dropoff, or call **1.800.742.5877**.



Hormones in Cosmetics

Inadvertent Transdermal Progesterone Intake

John White, MD, CM



“...90-95% of all the submitted creams... tested positive for progesterone.”

In this issue, we highlight an all too frequent finding noted in the results of the Female Hormone™ and ASI™ Panels. Figure 1 is an actual Cycling Female Hormone Panel™ result we recently processed. At first glance, the graphed results might suggest a fairly normal picture. Be alert, however, that for each separate test the computer may reset the plotting values on the estradiol and/or progesterone axes to accommodate the values measured. In the table of actual values that appears above the graph, note the excessively elevated progesterone levels in figure 1 (green shaded area) throughout both the follicular and luteal phases. Compare to the normal ranges

located below the patient values. The patient was not taking any prescribed supplementary hormones. Careful inquiry by her practitioner revealed she was an avid user of a “rejuvenating” face cream.

Our lab has noted such elevated progesterone values for a number of years. Several years ago,

we offered anonymous testing of suspect face creams for our clients. We were not surprised to find that 90%-95% of all the submitted creams, lotions, etc. tested positive for progesterone. In addition, we found considerable contaminating estrogens and androgens. Faced with the futility of this testing, it has been discontinued. The patients we tested were likely dosed unwittingly with progesterone (non-bioidentical) contained within creams or shampoos and for long periods of time. Such extra progesterone exposure prejudices accurate baseline results, and not only confuses the body's essential

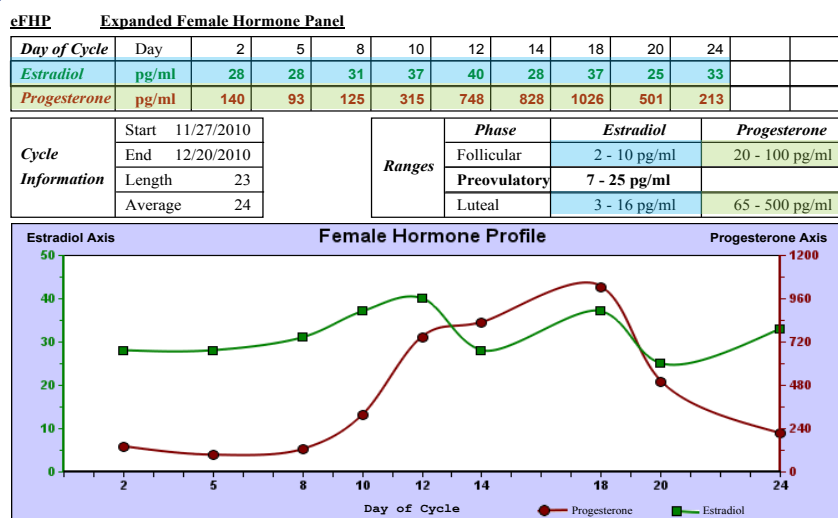
hormonal balance, but also proper therapeutic judgement.

Face creams and shampoos are classified legally as cosmetics, and as such, are not under the close purview of the FDA. Not only can manufacturers add progesterone to their products (up to 4%) but they are not required to list it on their labels. Be highly suspect of any product touted as “anti-wrinkle,” “anti-aging,” “rejuvenating” or “our own special formula.” One prominent face cream producer actually acknowledged adding progesterone (“nature’s own anti-wrinkle substance”) on its website; it was rapidly taken down. *Continued on next page*



Expanded Female Hormone Panel

Figure 1



Test	Description	Result	Ref Values
DHEA	Dehydroepiandrosterone	10 Normal	Adults (M/F): 3-10 ng/ml
TTF	Free Testosterone	68 Elevated	Borderline: 6-9 pg/ml Normal: 10-38 pg/ml

Serum levels of progesterone may not reflect salivary levels when progesterone creams are applied; typically salivary values more truly reflect the tissue levels.^(2, 3) This discrepancy may be due to variance in transport by the body of different products. Although most substances are carried in the blood stream, long chain lipids are transported preferentially by the lymphatics. Progesterone itself is lipophilic, as is any cream base containing it. Thus, lymphatic transport increases progesterone content in the tissue fluid and, consequently, in salivary measurements. Progesterone gels, on the other hand, are water soluble and may possibly achieve serum progesterone levels comparable to saliva values.⁽²⁾

Such elevated progesterone levels have also been noted in women prescribed progesterone cream, or who use various over-the-counter progesterone creams. Moreover, we have observed higher salivary levels when progesterone cream is used than when progesterone is administered orally or sublingually. This may be due to the intrinsic lipophilic property of the cream base and, possibly, the progesterone itself, which causes a variable amount of the applied progesterone to sequester in fat cells under the skin. Not only is the actual amount of progesterone reaching the blood stream unpredictable, but, if discontinued, it may take several months to leech entirely out of the fat stores beneath the skin.⁽¹⁾

Note as well in *figure 1* (blue shaded area) that, despite very high progesterone values, this patient has elevated estradiol in both follicular and luteal phases of her cycle. In the face of no known estradiol intake, her estrogen dominance state most likely

is the result of inadvertent intake or of inadequate natural or bioidentical progesterone to maintain a normal estradiol/progesterone balance. The high progesterone levels probably reflect the presence of isomers of natural progesterone that are not recognized by the body as truly natural and, hence, do not maintain the proper estradiol/progesterone balance.

“...elevated progesterone levels have also been noted in women prescribed progesterone cream...”

This patient's elevated estradiol may have some contribution from her relatively high DHEA (possible exogenous intake), which, in turn, may be a contributor to her elevated testosterone. Inquiry should be made, as well, regarding topical testosterone use by a male partner resulting in passive transfer.

Appropriate therapy in this case consists of stopping any progesterone creams, prescribed or inadvertent, or properly adjusting over-prescribed oral or transmucosal progesterone. Inasmuch as it can take months to rid the body of its subcutaneously stored progesterone, any oral or transmucosal bioidentical progesterone replacement program must be administered gradually up to the full dose to maintain appropriate progesterone balance in the body. A repeat Female Hormone Panel™ is recommended three to four menstrual cycles or months later, once the new replacement program has been established.

As a corollary to the above discussion, if a valid and accurate assessment of a woman's hormone status is desired, inquiry should be made prior to testing

regarding face cream use or other source, of progesterone; if present, the product should be stopped and testing performed at least six to eight weeks later. This advice applies equally for peri- and post-menopausal testing.

A woman with proper progesterone supplementation should not need any progesterone-containing face creams. Pure moisturizers (e.g. cetaphil) or, generally, baby moisturizers, lotions, shampoos are probably safe. The cosmetic industry probably is not adding progesterone to baby products yet!

Because it usually is impossible to gauge the extent of progesterone stores in a patient's body after transdermal use, the progesterone values reported by Diagnos-Techs™ constitute those measured in the laboratory. The ranges provided are not adjusted for any outside factors. Diagnos-Techs™ believes that it is incumbent upon the practitioner to interpret the basic data provided vis-à-vis the clinical picture presented by the patient, without any form of interpretive modification of the ranges by our laboratory. ①

REFERENCES

1. Ilyia, EF; McClure, D; Farhat, MY. Long Term Effects of Topical Progesterone Cream Application: A Case Study. *Intl J Pharm Compounding* (1998)
2. Stanczyk, FZ; Paulon, RJ; Subiz, R. Percutaneous Administration of Progesterone: Blood Levels and Endometrial Protection. *Menopause* (2005) 12:232-237
3. O'Leary, P; Feddema, P; Chan, K; et al. Salivary, But Not Serum or Urinary Levels of Progesterone Are Elevated After Topical Application of Progesterone Cream to Pre- and Post-Menopausal Women. *Clin Endocrin* (2005) 53:615-620

Educational Pathways @ Diagnos-Techs™

MEDICAL SUPPORT

Diagnos-Techs™ team of medical advisors is available to assist our licensed health care professional clients by answering questions about our laboratory tests and assisting with interpretation of test results. There is no additional fee to receive this service. Our medical support team consists of MDs and NDs offering over 100 years of medical experience. To speak to medical support call **1-800-878-3787**.

TELEPHONE CONSULTATIONS & OFFICE VISITS with our Medical Advisors

Telephone Consultations offer an overview of our test panels and reports to familiarize clients with how to use them, and offer an opportunity to ask questions.

Office Visits provide local clients the opportunity to receive information on testing and how to further integrate our lab into their practice. To schedule an appointment, please email Jessica at jessica@diagnostechs.com.

Diagnos-Techs™ offers several educational pathways to support our provider clients in their patient care. **Courtesy In-House Seminars, Office Visits and Telephone Consultations** are available for you to enhance your practice and stay informed. See info at left and below for details.

Seminars scheduled for Fall 2011

Resuming in September, Diagnos-Techs™ will offer comprehensive educational seminars designed to help clinicians integrate hormone assessment into their practice. Our next two seminars are scheduled for September 23 and October 28. Keep checking our website for more information, www.diagnostechs.com.



SPECIMEN DELAYS? Just Chill!

If a slight delay in returning a completed kit to the lab is anticipated, the specimens can be kept frozen or refrigerated up to three days until transported—with the exception of stool specimens. Freezing can kill bacteria and fungi and vitiate their effective culturing—an important part of the GI Health Panel™. If a delay in transportation is expected, stool specimens can be kept temporarily in a refrigerator (cooled but not frozen). For optimal reception and handling by the lab, send completed kits via UPS Monday through Friday.

Applicability of the Cycling Female Hormone Panel™ (FHP™)

The eleven-vial Cycling Female Hormone Panel™ (FHP™) should not be ordered for a woman who is not cycling in a normal fashion. Hormonal birth control is designed to prevent ovulation and, thereby, obvert a normal luteal phase rise of progesterone from a corpus luteum. This creates an abnormal cycle. To check the adequacy of hormonal birth control, a single-vial sample in mid-luteal phase using the Post Menopausal Panel™ (PostM™) will suffice to confirm the lack of progesterone elevation from a corpus luteum.

DID YOU KNOW?

DR. FRANZ HALBERG of the University of Minnesota, who coined the word **circadian**, is widely considered the “father of American chronobiology.”



Conferences & Tradeshows

If you are attending either of the events listed below, please visit our booth. We look forward to meeting you in person!

- **Catholic Medical Assoc.**—Oct. 6-8, 2011
80th Annual Educational Conference
Phoenix, AZ • <http://tinyurl.com/3lxqbnt>
- **A4M**—December 8-10, 2011
19th Annual World Congress on Anti-Aging Medicine & Biomedical Technologies • Las Vegas, NV
<http://tinyurl.com/3zyp7ed>

Chronobiology


Continued from front page



Chronobiology may be thought of as the study of the biology of the body over time through analysis of specific changes and aberrations of selected hormones, chemistries, etc. The father of this important approach to biologic testing is Dr. Franz Halberg, a scientist from Minnesota who emphasized the importance of examining periodic (cyclic) phenomena in living organisms.

Many of the diagnostic panels offered by Diagnos-Techs™ are designed specifically to reflect the chronobiology of the particular areas studied. The Adrenal Stress Index™ (ASI™) panel was the initial study offered by Diagnos-Techs™ (starting in 1989) and was designed specifically to assess the changes and perturbations of the circadian cortisol rhythm throughout the day. Additionally, it assays fasting and random (or post-prandial) insulin results. Most notably, the chronobiology of estradiol and progesterone during a woman's menstrual cycle are captured in the Cycling Female Hormone Panel™ (FHP™) offered by Diagnos-Techs™. Collecting saliva every two to three days (at the same time of day) in one of the eleven vials (frozen upon collection) can provide a clear picture of woman's essential cycling hormonal pattern. In its expanded form (eFHP™), five FSH and LH values (soon to increase to seven), measured around the time of ovulation, provide important information regarding the vital pituitary influence over ovulation. This panel is helpful for women with fertility concerns, symptomatic perimenopausal women

with intermittent estrogen surges (and possibly, estrogen dominance) and women with premenstrual syndrome.

Of course, follow-up testing with any of our panels after treatment provides the perfect opportunity to track over time a patient's problems and therapy. Diagnos-Techs™ prides itself not only in the accuracy of its findings but also the capability to observe the temporal variations of these findings to better understand your patient. 

Diagnos-Techs™ Lab News

Announcing Improvement in the Expanded Female Hormone Panel™ (eFHP™)

The Expanded Female Hormone Panel™ (eFHP™) adds evaluations of the pituitary hormones, follicle stimulating hormone (FSH) and lutenizing hormone (LH), to the regular FHP™ for cycling women.

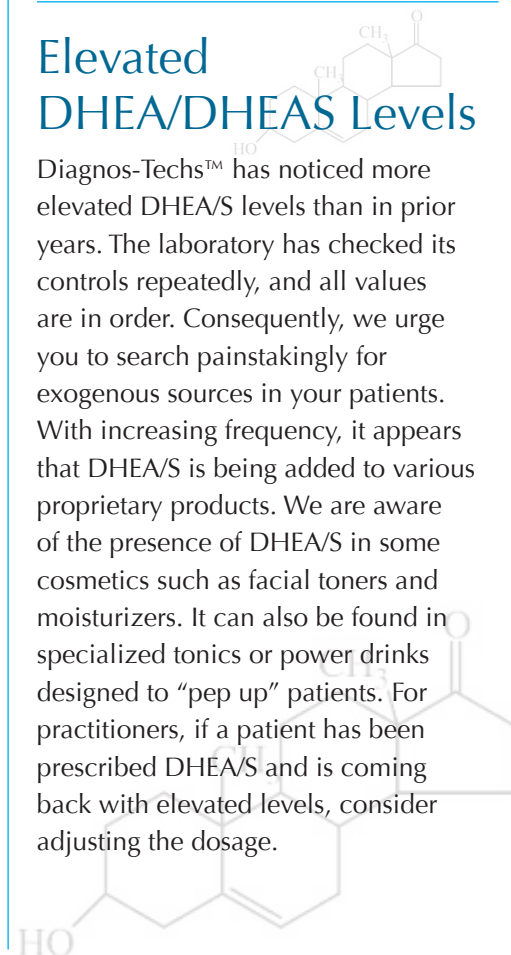
Currently, five assessments of each hormone are reported, centered around the estimated time of ovulation. These assessments are valuable adjuncts in assessing a woman's cycle for fertility and ovulation. Considering variations in the timing of ovulation and the length the cycles exist, they may not be covered by or included in the current five reported hormone values. Diagnos-Techs™ will soon increase the number of values of FSH and LH reported to the seven middle values. This improvement will provide a broader coverage of FSH and LH values to further elucidate any vagaries encountered in a woman's cycle.

Hormone Supplementation & Salivary Hormone Testing

When saliva testing is used to assess the status of a patient taking hormones, avoid ingesting or applying the hormones on the day of the test until the collection is finished. Moreover, with sublingual or buccal (transmucosal) hormone replacement, for three days prior to testing the product should be swallowed with a glass of water, in order to avoid contamination of the saliva. Any dose on the evening prior to testing should be avoided. On the day of testing, the usual transmucosal route can be resumed—after the saliva collection is finished.

Elevated DHEA/DHEAS Levels

Diagnos-Techs™ has noticed more elevated DHEA/S levels than in prior years. The laboratory has checked its controls repeatedly, and all values are in order. Consequently, we urge you to search painstakingly for exogenous sources in your patients. With increasing frequency, it appears that DHEA/S is being added to various proprietary products. We are aware of the presence of DHEA/S in some cosmetics such as facial toners and moisturizers. It can also be found in specialized tonics or power drinks designed to “pep up” patients. For practitioners, if a patient has been prescribed DHEA/S and is coming back with elevated levels, consider adjusting the dosage.





Why Choose Diagnos-Techs™?

High Quality Laboratory Service

Diagnos-Techs™ maintains superior test quality by using a daily program of comprehensive quality assurance. All quantitative results are obtained from test runs which are in compliance with industry standard testing protocols from the Clinical Laboratory Standards Institute (CLSI), World Health Organization (WHO)* and similar organizations. A minimum of two control materials are included with each run. Each and every result is reviewed by supervisory personnel to provide accurate results for initial tests as well as highly precise results in follow-up tests, ensuring the highest standard of clinical management.

*WHO is the World Health Organization that sets international standards for various parameters in medical practice. World Health Organization (WHO) has designated The Joint Commission and Joint Commission International (JCI) as the world's first WHO Collaborating Center dedicated solely to patient safety.



Adama Trimnell, DVM, PhD, uses an immunofluorescent microscope to detect antigens for the GI Health Panel in the DTI Lab.



BILLING ASSISTANCE • ICD-9 & CPT Codes

Many providers have a cash-only practice and advise their patients with insurance to file their own individual insurance claims. The *Insurance Billing Department* at Diagnos-Techs™ stands by to provide assistance. In addition, the provider's office can often help their patients with insurance at the time

of the office visit by supplying the patient with the appropriate ICD-9 and CPT codes for the tests ordered. These are provided to each office on the three-page foldout entitled *Test and Fee Schedule 2010* sent out by Diagnos-Techs™. It is also available for download and printing at our website, www.diagnostechs.com.

Director of Medical Support


Continued from front page


“...I am pleased to have a second career at Diagnos-Techs.”

Coast Guard (US Public Health Service) and thereafter qualified in General Surgery, and Cardiovascular and Thoracic Surgery at the McGill University Teaching Hospitals. I further qualified in Pediatric Surgery at Johns Hopkins, spent ten years on staff there, and finished my academic career as a Professor of Pediatric Surgery at various institutions. I am proud to have over 175 peer reviewed scientific publications as primary or coauthor. After retiring in Seattle near my children and grandchildren, I am pleased to have a second career at Diagnos-Techs™.

Our *Medical Support Department* consists of a blend of fine medical and naturopathic physicians who are ready to assist our clientele with expert interpretation of the sophisticated tests and panels we provide and occasionally with guidelines toward appropriate therapy. Inasmuch as we have no doctor/patient relationship with those tested, have not taken a history or performed a physical exam, and are generally not licensed to practice in a client's particular state, we can not provide

specific treatment recommendations. If requested, we are pleased, however, to suggest appropriate therapeutic pathways.




On behalf of our entire *Medical Support Department*, I pledge that we will continue to provide the outstanding support you deserve and to improve whatever and whenever necessary. 



DiagnosTechs™
THE LEADING LAB IN SALIVA TESTING SINCE 1989

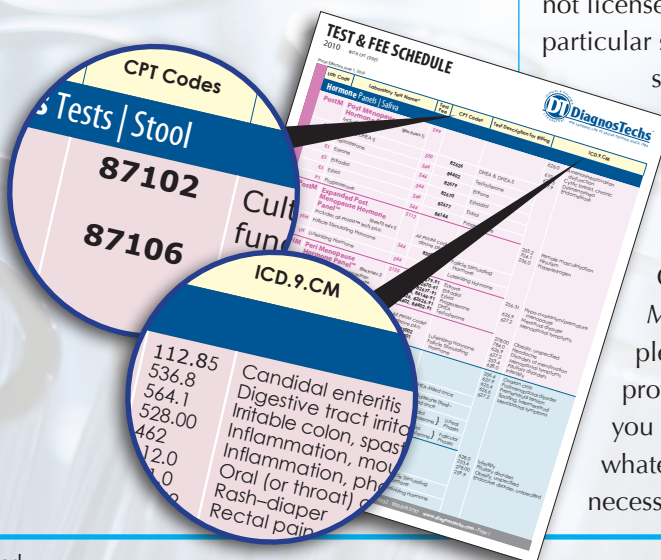
Issue #9 Chronobiology Letter is published quarterly by Diagnos-Techs™ Laboratory, Inc. in Kent, WA, USA as an educational resource for our health care clients. The content in this newsletter is for informational purposes only and is not to be construed as medical advice.

Diagnos-Techs™, Inc.
19110 66th Avenue S.
Building G
Kent, WA 98032 USA

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DIAGNOS-TECHS™ RESOURCES FOR YOU ▼



Billing

Courtesy Service

FROM OUR TEAM OF INSURANCE SPECIALISTS

Our dedicated team of Insurance Specialists is trained to assist you with insurance-related questions. We avoid payment processing challenges by helping you and your patients navigate the maze of test codes and fees.

As a courtesy, we will submit claims to most insurance companies at our clients' and patients' requests. In addition, we are able to bill insurance carriers for all referring doctors, nurse practitioners and registered nurses. We are able to advise you on which services are billable. Although we are a non-contracted provider with all insurance companies (with the exception of Medicare), most insurance carriers offer coverage on our services and are billable. Depending on a patient's benefit plan, insurance companies usually cover our tests at the maximum allowable rates so there are no out-of-pocket expenses.

Patient Insurance Disclaimer

Diagnos-Techs™, Inc. is a non-contracted provider with all insurance companies. Please verify your out-of-network benefits (including out-of-network deductibles and co-insurances) by contacting your insurance carrier. Diagnos-Techs™, Inc. will bill your insurance at the retail price per line item. If deductibles and/or co-insurances are applied, Diagnos-Techs™, Inc. is obligated by law in the State of Washington to collect.

HIPAA Compliance

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) requires us to protect and maintain the privacy of our patients' identifiable health information. The standards are meant to improve the efficiency and effectiveness of the nation's health care system. We are committed to implementing appropriate administrative, technical and physical safeguards to protect the privacy of Protected Health Information. For more information, go to www.diagnostechs.com and click About Us/Notice of HIPAA Privacy Practices.



Technical Customer Service

Tips for Success

- **Sign up to access results online.**
Call Customer Service for password, 1-800-878-3787.
- We must have at least **two** forms of written patient ID, **name** and **date of birth** on **all vials** and **order forms** to process samples.
- **Patients should *not* contact the lab with test related questions.**
Please advise patients to consult with you if they have any questions pertaining to collection. Medical support is available for provider questions about results or treatment suggestions at 1-800-878-3787.
- **Review patient medication list.**
This will help your patients to understand what to avoid before taking our tests. We do not discuss medications directly with patients.
- Have your **account number** or **accession number** ready before you call.
- **Tips for saliva production.**
In order to produce enough saliva, suggest to your patients to chew dental grade paraffin wax.



Contact Us

How to Reach Us

Business Hours

7:30am–5:00pm
Pacific Standard Time (PST)
Monday through Friday,
except major holidays

Corporate Address

19110 66th Avenue S., Building G
Kent, WA 98032 USA

Customer Service

p 800-878-3787 **f** 425-656-2871
p 425-251-0596

Accounting

f 425-264-0612
email billing@diagnostechs.com

Shipping

p 800-878-3787 **f** 253-398-2449

Technical Services

p 800-878-3787 **f** 425-251-0637

Lab Address

Sample Processing
6620 S. 192nd Place, Building J-106
Kent, WA 98032 USA



Please visit us online at
www.diagnostechs.com

www.facebook.com/diagnostechs



Shipping

Free UPS Return Shipping on returned domestic test kits



STORAGE & MAILING INSTRUCTIONS FOR ALL SPECIMENS

- ☐ Ship samples on the same day as last sample collection (preferred).
- ☐ If not possible, refrigerate samples and ship within 3 days.
No ice bags are required during shipping.
- ☐ Write the patient's name and address on the outside of box.
- ☐ Include all samples, test form and, if applicable, a check or a copy of the front and back of insurance card together inside the supplied box. Please be sure to seal the box with clear tape before shipping.

- **US Domestic:** Deliver completed test kit box to any **UPS** location. www.UPS.com/dropoff Return shipping to Diagnos-Techs™ is **PRE-PAID**. Kits will arrive within three days of shipment.
- **International:** Delivery charges still apply. **International deliveries should be addressed to the physical address only, which is located to the right. Do not address to the PO Box.** Deliveries can be made Monday through Friday via a **private courier of your choice.**

**INTERNATIONAL
COURIER SHIPPING**
Diagnos-Techs™, Inc.
Sample Processing
6620 S. 192nd Pl., #J-106
Kent, WA 98032
p 425-251-0596



DiagnosTechs™

THE LEADING LAB IN SALIVA TESTING SINCE 1989

19110 66th Avenue South, Building G
Kent, Washington 98032 USA

www.diagnostechs.com



September 2011

National Health Observances

Sept 13

- National Celiac Disease Awareness Day

Sept 24

- Family Health & Fitness Day®

Sept 28

- National Women's Health & Fitness Day™

September is also...

- National Alcohol & Drug Addiction Awareness Month
- Prostate Cancer Awareness Month



Flexi-Matrix™ Customized Test Panels

Flexi-Matrix™ test kits allow you to order individualized test combinations, with the exception of BHP™, FHP™, eFHP™, PeriM™ and ePeriM™ panels. When combining panels, be sure to include the individual tests listed under each of the panels. Flexi-Matrix™ customized test kits may be **the most economic way** of customizing test panels and profiles to meet your clinical needs, possibly saving you **20-70%** off individual test fees.

- **Choose 3 or more** individual tests from the list shown on pages 4-6 of the *Test and Fee Schedule*.
(Excludes DPD Bone Marker Test and CS3 Swab Culture for Yeast.)
- **Be sure to read** detailed instructions and fill out the requisition form included in each collection kit.
- **You will always receive the lower price** when your customized panel is identical to a standard panel.

Flexi-Matrix™

"Build Your Own Panel"

- Insulin x2
- Gluten Ab

- Chymotrypsin
- Tape Worm
- Round Worm

- Estriol
- Progesterone
- FSH

- Androstenedione
- Estrone

ASI

Adrenal Stress Index™

- Cortisol x4
- DHEA + DHEA(S)
- Insulin x2
- 17-OH Progesterone
- Gluten Ab
- Total Secretory IgA

GI-02

Expanded Gastrointestinal Health Panel™

- Stool Culture for Yeast
- Chymotrypsin
- Ova and parasites
- Occult Blood
- Bacterial Stool Pathogens
- Fecal pH
- Clostridium difficile Antigens
- Total Intestinal SIgA
- Tape Worm
- Giardia Antigen
- Intestinal Lysozyme
- Cryptosporidium Antigen
- Alpha Anti-Chymotrypsin
- Amoeba histolytica Ab
- Gluten Intolerance Test
- H. pylori Ab
- Round Worm
- Tissue Worm

ePostM

Expanded Post Menopausal Hormone Panel™

- DHEA + DHEA(S)
- Testosterone
- Estrone
- Estradiol
- Estriol
- Progesterone
- LH
- FSH

eMHP

Expanded Male Hormone Panel™

- DHEA + DHEA(S)
- Androstenedione
- Testosterone
- Dihydrotestosterone
- Estrone
- Progesterone
- LH
- FSH