ChronoBiology Letter

DiagnosTechs

November 2011 📔 10th Edition

Diagnos-Techs[™]

Clinical & Research Laboratory Quarterly Newsletter

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Medical Support Group

John J. White, MD, CM

Recent callers for advice and interpretation of results have probably noticed two new voices in our Medical Support group at Diagnos-Techs[™]. As well, you certainly would have been as pleased and impressed with them as we are to have them with us. They are:

Brandy Webb, ND



Dr. Webb received her Doctorate of Naturopathic Medicine from Bastyr University

after earning her biochemistry degree from Seattle University. While pursuing her pre-medicine studies, Dr. Webb worked at the Fred Hutchinson Cancer Research Center studying allogeneic bone marrow transplantation. Following medical school, Dr. Webb promptly became a teaching fellow, clinical resident, and ultimately an instructor at Bastyr and other institutions teaching advanced



Diagnos-Techs[™] is going **Paperless!**

In an effort to be more mindful of the environment, we will now be distributing an electronic version of our quarterly newsletter, **ChronoBiology Letter**. If you do not have an email address listed on your account, please call **Client Services at 1.800.878.3787** to add your email address.

If you prefer to receive a printed copy of our ChronoBiology Letter, please email us at diagnos@diagnostechs.com.

doctoral courses in pharmacology, gastroenterology, clinical diagnosis, and gynecology. She also practices privately, specializing in functional medicine and endocrinology, with particular expertise in hormonal restoration and fertility optimization in both men and women. Dr. Webb has authored health-related articles, delivered community-wide lectures, and been featured in local radio programs and national print publications.

Andrew Allshouse, ND



After majoring in biochemistry at the University of Washington, Dr. Allshouse earned his

Doctorate of Naturopathic Medicine from Bastyr University with a focus on homeopathic medicine, diagnostics, and mental health. Dr. Allshouse is an experienced Emergency Medical Technician and has volunteered at the Seattle Crisis Clinic for 6 years. While leading the anatomy department at Everest College, he received national recognition. He developed a locally broadcast television show, The Naturopathic Perspective, wherein he fielded health-related telephone calls from the public on live TV. Dr. Allshouse also has established his own insurance-based private practice specializing in preventative counseling and mental health. Since joining the Medical Support department at Diagnos-Techs™ he continues to practice, remains active in his church, and volunteers with The American Red Cross.

ChronoBiology LETTER

Bone Health Panel[™](BHP[™])

John J. White, MD, CM Andrew Allshouse, ND Kamal Henein, MD

ne of the lesser known and appreciated tests offered by Diagnos-Techs[™] is the Bone Health Panel[™]. It utilizes saliva samples to assess pertinent hormone levels and an aliquot of urine to assay Pyrilinks-D. No trips to a laboratory or radiation exposure are involved, and costs are considerably less. The test is accurate and can be used to monitor the effects of any bone health program.

As background, the interplay between bone formation and resorption is a continuous, lifelong process that favors bone formation in the early years of life, leading to a peak bone mass at approximately 20 to 30 years of age. From then on, total bone mass gradually declines in both men and women. Women generally experience an increased rate of bone loss in the post-menopausal years, largely due to declining estrogen levels. The cycle of bone remodeling starts with osteoclasts (resorption cells) eroding bone surfaces and forming cavities. The collagen peptides that result from bone resorption have pyridinoline structures that can be assayed in urine as a measure of bone resorption rate.

At the same time, osteoblasts (bone-forming cells) secrete bone matrix proteins. Ninety percent of these are collagen type I with other minor proteins; osteocalcin, the isoenzyme alkaline phosphatase, and procollagen I extension peptides are also secreted

Low Levels of:	High Levels of:	Other:
17-B estradiol,	cortisol,	low body weight,
progesterone,	parathyroid hormone,	celiac disease,
testosterone, calcitonin,	glucose load (diabetes),	alcoholism,
vitamin C, vitamin D,	thyroid hormone,	rheumatoid arthritis,
physical activity	FSH	multiple myeloma

into the general circulation. The final step in the cycle is the mineralization of the matrix protein by calcium salts. Additional mechanical bone tensile strength is attained through the formation of pyridinium cross-links (pyridinoline [Pyd] and deoxypyridinoline [DPD]) between the neighboring mature collagen fibrils.

Alteration in the activity of osteoblastic and osteoclastic cells represents the final pathway through which diverse stimuli, including hormones, affect bone balance. Successful bone maintenance requires continued attention to factors that influence bone acquisition: diet, physical activity, and sex hormone status, with possible deficiency of one not compensated by the others.

Osteoporosis is defined as "reduction in bone mineral density, leading to fractures after minimal trauma," and osteopenia as "any decrease in bone mass below normal."⁽¹⁾ These processes progress inevitably starting age 30-40 and appear to be more severe in women. They result from a dynamic chronic imbalance among a variety of factors (see Table 1, above).

Although the pathogenic events involved in the development of osteopenia, and its progression to osteoporosis, are relatively irreversible, they can be slowed down and ameliorated by early detection and intervention. Traditionally, diagnosis has relied on bone densitometry (mineralized bone mass assay) using radioactive or radiographic techniques performed at a referral facility. Noninvasive methods to estimate bone mineral density are now available to identify high-risk patients who have not yet sustained a fracture. They include a number of specific urinary assays of bone resorption markers for the diagnosis and follow-up of osteoporotic patients.

Assays of Pyrilinks-D, pyridinoline, and N-terminal cross-linked peptides (NTX) in urine have been advanced as sensitive and specific markers for bone resorption. Pyrilinks-D is specific



for bone resorption and does not measure collagen degradation;^(2,3,4) it has a 96-98% range of accuracy.^(5,6) Pyrilinks-D assay has demonstrated precision and accuracy equal or superior to cross-linked N-telopeptides (NTX) and linear C-telopeptides of type I collagen (CTX).^(2,6) It is a better predictor of bone loss than invasive serum osteocalcin measurements.⁽⁴⁾ As well, Pyrilinks-D measurements correlate well with treatment.^(4,6,7) For these reasons, Diagnos-Techs[™] has selected the Pyrilinks-D assay as a meaningful assessment of bone loss and its treatment. In men and women 40-80 years of age, a Pyrilinks-D (DPD) value exceeding 7.3 nmol/mmol creatinine signals osteopenia or osteoporosis.

Although the Pyrilinks-D urinary assay may be ordered separately, the Bone Health Panel[™] (BHP[™]) offered by Diagnos-Techs[™] includes an assessment of those hormone values of a patient that underlie bone metabolism. They include:

Estradiol(10,11)

- Limits bone elongation in adolescents and prevents bone loss in adults.
- After menopause, very small amounts (if any) of estrogens are secreted by the ovaries.
- Low estrogen levels cause diminished bone deposition.
- Low estrogen levels increase the number and activity of osteoclasts.

Progesterone⁽¹²⁾

• Promotes new bone formation and deposition.

Testosterone⁽¹³⁾

• Helps reduce bone loss and has a role in bone formation.

Cortisol^(14,15)

- Glucocorticoids directly inhibit bone formation by decreasing cell proliferation and the synthesis of DNA, proteins, and collagen.
- Glucocorticoid-induced bone loss results from lower activity and higher death rate of osteoblasts on the one hand, and from increased bone resorption due to prolonged life span of osteoclasts on the other.
- Glucocorticoids may potentiate the proresorptive actions of parathyroid hormone and vitamin D on bone, which contribute to net bone resorption.

DHEA/DHEA-S⁽¹⁶⁾

- Enhances bone deposition and remodeling.
- Decreases bone resorption and increases bone formation.

FSH^(17,18)

- Bone loss during or after menopause has been attributed to a drop in estrogen levels. Recent studies show that high FSH is associated with hypogonadal bone loss.
- In early menopause, FSH levels show a sevenfold increase over values found in young menstruating women.
- In perimenopause and postmenopause, FSH is correlated with:
- Bone loss and osteoporosis
- Sleep disturbances
- Hot flashes and night sweats

The information provided by the Bone Health Panel[™] (BHP[™]) constitutes a valuable data base upon which to construct an appropriate treatment plan for patients with osteopenia or osteoporosis. Appropriate correction of hormonal imbalance, coupled with calcium and vitamin supplementation or pharmacological intervention, can provide the under-pinning of successful therapy.

Follow-up assessments every six to twelve months can provide ready evaluation of the selected therapy.

With regard to therapeutic approaches,

the *Institute of Medicine* recently reported on dietary reference intakes for calcium and vitamin D, emphasizing their real benefit for skeletal health but inconsistent and inconclusive affect on extra-skeletal health problems (e.g., cancer, cardiovascular disease, diabetes, and autoimmune disorders).⁽¹⁹⁾ *The Endocrine Society* has presented practice guidelines for the evaluation, treatment, and prevention of vitamin D deficiency.⁽²⁰⁾



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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™ On the Road

Conferences & Tradeshows If you are attending the event listed

below, please visit our booth. We look forward to meeting you in person!

A4M—December 8-10, 2011
 19th Annual World Congress on
Anti-Aging Medicine & Biomedical
 Technologies • Las Vegas, NV
 http://tinyurl.com/3zyp7ed

Bone Health, REFERENCES

Continued from page 3

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Hormones in Cosmetics—An Update

John J. White, MD CM Brandy Webb, ND

In the previous issue of *ChronoBiology Letter* (August 2011), we stated that "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 label." Further research, including direct communication with the FDA, compels clarification of this statement.

Our original statement was partially informed by a *Federal Drug Administration* advance notice of proposed rulemaking (ANPRM) pertaining to the presence of hormone ingredients in cosmetic products, which was published in the Federal Register on September 9, 1993 (58 FR 47611). At that time, the FDA proposed to allow up to 0.5% pregnenolone acetate and 5 mg/oz progesterone in cosmetic products.

Furthermore, 58 FR 47611 prohibited

cosmetic products from having the term "hormone" appear anywhere on the label or ingredient list. This prohibition created a paradox wherein the FDA proposed that, while the presence of progesterone or pregnenolone was allowable in cosmetics, apparently disclosing that information to the consumer was not.

Ultimately, this proposal was withdrawn before it was formally enacted due to the "regulatory backlog" that existed within the FDA, but not until over a decade later on November 26, 2004 (69 FR 68831). Moreover, during the period that 58 FR 47611 was still in proposal status, the stated safe upper limits regarding progesterone and pregnenolone were promulgated within the FDA and eventually incorporated into the official *Guide to Inspections of Cosmetic Product Manufacturers* (available at www.fda.gov).

At present, as communicated directly to us by FDA personnel, it is illegal to list any hormones on the label of any cosmetic, and it is also illegal for any product actually to contain hormones. Compliance with these directives and any potential harm from the addition of hormones to cosmetics remains for the FDA Office of Compliance to determine.



Announcing the New **Diagnos-Techs**[™] **Catalog**!

Diagnos-Techs[™] is excited to provide a new catalog for all clients. Colorful, compact and easy to read, this new catalog will serve as a handy resource with detailed information about test panels, ordering, shipping, contact information, and so much more. Please expect your copy of the catalog included with your next test kit order. If you do not receive a copy, please contact Technical Customer Service at **800-878-3787** to request a copy. The catalog is also available to view online at **www.diagnostechs.com/catalog.**

Cycling Female Hormone PanelTM (FHPTM)

Timing of Collections

Appropriate collection timing for the 11 vials in the Female Hormone Panel[™] (FHP[™]) may be challenging. Each kit contains two proposed collection calendars: one for a "regular" cycle of 28-32 days, and one for an "extended" cycle of 33-42 days. These are guidelines and can be modified as necessary by a practitioner. For a woman with a short cycle, the timing of collections can be compressed to accommodate the shortened time. At times, however, despite the most careful planning, a menses may occur before the planned collection vials are finished. Be aware that 8-9 vials are generallt sufficient to provide an accurate picture of the hormonal changes during that particular cycle. Collection of any extra vials from the next cycle provides no meaningful information about the cycle under study and introduces spurious information to our computers, resulting in skewed graphing of that cycle's estradiol and progesterone, as well as erroneous calculations for the information provided on page two of the report. Once menses arrives, resist the temptation to fill the unused vial(s); do NOT submit them, lest they contribute to an inaccurate picture of your patient's cycle. In addition, should a patient have a bleeding episode or "menses" midway through a collection (before 8-9 vials have been filled), discard the collection and perform a new collection with the next true menses.

LABORATORY ADVISO

GI Panel

First collect the 1st B stool collection vial; collect the 2nd B vial and A vial just prior to shipping.

The kit for the GI Panel[™] from Diagnos-Techs[™] contains two types of vials for stool collection: one "A" vial and two "B" vials. The B vials contain a preservative and are used for the microscopic ova and parasites (O&P) exams, as well as the various tests run on desiccated stool. They have a greater stability. The A vial containing sterile saline is used for the stool cultures (bacterial and fungal). Unfortunately, it has a lesser stability (non-refrigerated) of 4-5 days. Consequently, patients doing these tests should be advised to fill the B vials first, and then the A vial just prior to shipping.

Salivary IgA

Added to the Food Intolerance Panel™ (FIP™).

The Food Intolerance Panel[™] from Diagnos-Techs[™] measures salivary secretory immunoglobulin A (SIgA) antibodies to casein (milk), soy, albumin (egg), and gliadin (gluten). Unlike the other immunoglobulins, which are primarily in the blood compartment, IgA antibodies are derived from the intestinal food antigens/IgA defense mechanisms of the gut. The mucosa of the gastrointestinal tract is the major source of IgA in the body, and the strength of the IgA antibody response is related to the amount of IgA present in the system. Depleted IgA levels will be reflected as low IgA antibody titers for the measured antigens. In order to place the food sensitivity antibodies in the proper perspective, consider ordering a total salivary IgA (SIgA) level as well as the four food IgA antibodies (using the Flexi-Matrix™ kit). This datum can help obviate false negative value interpretations.

TECHNICAL CUSTOMER SERVICE

Did you know that every day Diagnos-Techs™ receives many calls from patients who have medical-related questions? Examples of such questions include whether to discontinue medications prior



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🛞 Printed on recycled paper.

to testing, what kinds of treatment would be appropriate for medical conditions, and general interpretation of test results. These types of questions are best answered by a healthcare practitioner who knows the medical background of his or her individual patient. We encourage practitioners to stress to their patients that they need to contact them directly regarding these matters. We do have doctors on staff who are able to answer medical questions, but they are only able to speak directly to a licensed healthcare provider. A healthcare provider can always arrange to have a three way consultation between him or herself, our doctor in Medical Support, and the patient. Free consultations are available between 7:30am and 5:00pm Pacific Time.

GREEN TOPPED COLLECTION TUBE CONFUSION

Confusion apparently has arisen over some green-topped



collection tubes. Diagnos-Techs™ uses two green-topped collectors: a green-topped saliva vial (labeled "F/L"), and a green-topped urine collector (labeled "U"). The "U" container is wider than the standard saliva vial and is used for collecting an aliquot of urine to measure D-pyrilinks in the Bone Health Panel[™] (BHP[™]). This is the only urine assay offered by Diagnos-Techs™. The "F/L" greentopped vial contains a preservative and is used for collecting saliva for the expanded part of all the hormone tests (i.e., to allow measurement of the pituitary hormones FSH and LH). Recently, the lab has received urine samples in the "F/L" vial, and NOT for the bone density testing. Please advise your patients that simply because an "F/L" vial might be included in the kit (Flexi-Matrix[™] or standard panel), it should be used only if expanded (FSH and LH) results are desired. For all other hormone tests, the "H" vial (blue topped) suffices. The wider greentopped "U" container is the only one used for urine and is only used when a Bone Health PanelTM (BHPTM) or DPD test is ordered.



Did you know?: Diagnos-Techs™ makes return shipping convenient

and easy! Log on to www.diagnostechs.com/ WebReturns to learn more.

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.



Tips for Success

- Have your account number or accession number ready before you call.
- 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.
- 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

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

Accounting

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

Shipping

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

Technical Services

p 800-878-3787

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

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 the 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 OR the UPS shipping label (US only).
- 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 business days of shipment.
- International: Delivery charges apply. Visit our website for access to discounted return shipping via UPS. Deliveries can also be made Monday through Friday via a private courier of your choice. International deliveries should be addressed to the physical address only, as noted above and to the right. Do not address to the PO Box.

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

INTERNATIONAL



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www.diagnostechs.com

National Health Observances

NOVEMBER 2011



American Diabetes Month Lung Cancer Awareness Month Healthy Skin Month

Prematurity Awareness Month

- 14-20 Get Smart About Antibiotics Week17 Prematurity Awareness Day
 - 18 Great American Smokeout
 - 19 Survivors of Suicide Day
- 20-26 Gastroesophageal Reflux Disease Awareness Week

DECEMBER 2011

- I World AIDS Day
- 4-10 Handwashing Awareness Week

TORMALE PANE

JANUARY 2012

Cervical Health Awareness Month Birth Defects Prevention Month Glaucoma Awareness Month Radon Action Month Thyroid 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 economical way of customize test panels and profiles to meet your clinical needs, possibly saving you 20-70% off individual test fees, and are required for testing by the laboratory.

- 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.

ASI	GI-02			ePostM	eMHP
Adrenal Stress	Expanded Gastrointestinal			Expanded Post	Expanded Male
Index™	Health Panel™			Menopausal	Hormone Panel [™]
 Cortisol x4 	Stool Culture for Yeast	Giardia Antigen		Hormone Panel™	• DHEA + DHEA(S)
• DHEA + DHEA(S)	 Chymotrypsin 	 Intestinal Lysozyme 	e	 DHEA + DHEA(S) 	 Androstenedione
• Insulin x2	 Ova and Parasites 	 Cryptosporidium A 	ntigen	Testosterone	Testosterone
17-OH Progesterone	Occult Blood	 Alpha Anti-Chymo 	trypsin	Estrone	Dihydrotestosterone
• Gluten Ab	Bacterial Stool Pathogens	Amoeba Histolytic	a Ab	 Estradiol 	• Estrone
Total Secretory IgA	• Fecal pH	Gluten Intolerance	e Test	• Estriol	Progesterone
	Clostridium Difficile Antiger	ns • H. Pylori Ab		 Progesterone 	۰LH
	Total Intestinal SIgA	Round Worm		۰LH	• FSH
	• Tape Worm	Tissue Worm		• FSH	

Flexi-Matrix™

- "Build Your Own Panel"
- Insulin x2
 Gluten Ab
- Chymotrypsin
- Tape Worm
- Round Worm
- Estriol
 Progesterone
- FSH
- Androstenedione
- Estrone