

**PH** PERQUE INTEGRATIVE HEALTH ACADEMY

WOMEN'S HEALTH CHALLENGES DURING PANDEMICS AND BEYOND | A PHYSIOLOGY BEFORE PHARMACOLOGY APPROACH

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PREDICTIVE BIOMARKERS | RUSSELL JAFFE MD, PhD, CCM

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**PREDICTIVE BIOMARKERS (PB) FOR PROACTIVE, PERSONALIZED CLINICAL CARE**

**PB** tests & **functional** assessments include all **epigenetic risks**

**Least risk-highest gain** goal values *rather* than **normal** lab values

**High sensitivity predictive biomarkers** = personalized and higher quality clinical care.

**Individualized** supplementation based on **predictive biomarkers**

**PH** PERQUE INTEGRATIVE HEALTH ACADEMY **Let's Rethink Health together!**

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## FUNCTIONAL/GOAL VALUES VS. USUAL/ 'NORMAL' LAB RANGES

**Predictive goal values**

- All-cause morbidity and mortality then compared to *best outcome value*
- Quality of life today and lifespan are *optimized and personalized*
- Net costs of care are reduced
- Least risk / highest gain values = goal values = *best outcome*

**Conventional lab values**

- Useful only for population studies
- Compare to "usual" or "normal" *statistical* ranges of analyte
- Age, gender, SES based public health value (*little* for individuals)
- Higher proportions of *unwell people* represented in longer lived cohort

**PH** PERQUE INTEGRATIVE HEALTH ACADEMY  
 RS Galen and SR Gambino, *Beyond normality: The predictive value and efficiency of medical diagnosis* (New York, NY: Wiley, 1975), 10-40.

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## PREDICTIVE BIO-MARKER TESTS TO DETERMINE YOUR FUNCTIONAL AGE

Test Name	Test Descriptions	Predictive Goal Values
Hgb A1c (HbA1c)	Sugar/insulin/energy... AGE	<5%
hsCRP (hsC reactive protein)	Repair & inflammation immune status	<0.5 mg/L
HCY (hsHomocysteine)	Detox, epigenetic, methylation... Sulfur	< 6 µmol/L
LRA (hslymphocyte response assay)	Immune memory/immune tolerance	No reactions
Ur pH >6 <sup>+</sup> rest (1 <sup>st</sup> AM Urine pH)	Mineral status & cell acid/alkaline balance	6.5 – 7.5
Vitamin D (25-Hydroxy-cholecalciferol)	Cell communication status	50 – 80 ng/mL
Omega-3 Index (Omega 3:6 EFA ratio)	Omega 3:6 ratio; EFAs	>8%
8-OHdG (8-Oxo-Guanine)	Oxidative stress/antioxidant nucleus status	<5 ng/mg creatinine

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## VALUES: 'NORMAL' VS PREDICTIVE GOAL

	Normal Values	Predictive Goal Values
Hgb A1c	4-6% Therapy Goal: <7%	<5%
hsCRP	1-3 mg/L	<0.5 mg/L
Homocysteine	4-17 µmoles/L	<6 µmoles/L
LRA	NA	Immune Tolerance
1 <sup>st</sup> AM urine pH	4.6-8	6.5-7.5
Vitamin D	20-40 ng/mL	50-80 ng/mL
Omega 3 index	ND	>8%
8 OH dGuanosine	4.6-19.2 ng/mg (11.9+/-7.3 ng/mg)	<5ng/mg creatinine

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## LIFETIME HEALTH: 92% CHOICES

Modified from: Baccarelli A, et al. Cardiovascular Epigenetics: Basic Concepts and Results From Animal and Human Studies. *Circulation: Cardiovascular Genetics*. 2010; 3: 567-573.  
 Jaffe R, Nash R, Ash R, Schwartz N, Corish R, Born T, Lazarus H. An Equation of Health: Role of Transparency and Opacity in Developing Healthcare Efficacy Measures and Metrics. *J Management Development* 2007; 26 (5): 441-458.  
 Jaffe R. The Alkaline Way: Integrative Management of Rheumatoid Arthritis and Other Autoimmune Conditions. In: Watson RR, Preedy V, Eds. *Bioactive Food as Interventions for Arthritis and Related Inflammatory Diseases*. Academic Press, 2013. p 97-112.

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 92% EPIGENETIC

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## HGB A1C / HGA1C PREDICTS SURVIVAL

Blood Glucose (mmol/L)	HbA1c (%)	Probability of Living Ten Years
5.4	5%	99%
7.0	6%	93%
8.6	7%	87%
10.2	8%	81%
11.8	9%	75%
13.4	10%	69%
14.9	11%	63%
16.5	12%	20%

Bunn HF, Hanev DN, Gabbay KH, Gallop PM. Further Identification of the Nature and Linkage of the Carbohydrate in Hemoglobin A1c. *Biochem Biophys Res Commun*. 1975; 67(1): 103-109.  
 Luzzatto-Gordon C et al. Dietary Advanced Glycation End-Products and Aging. *Nutrients* 2010; 2: 1247-1265.  
 Hinzmann R, Schliager C, Tran C T. What Do We Need Beyond Hemoglobin A1c to Get the Complete Picture of Glycemia in People with Diabetes? *Int J Med Sci* 2012; 9(9):888-891. doi:10.7155/ijms.4420  
 Greenwald TL, Seaman TE, Ruff CD, Karamangola A, Singer BH. Combinations of Biomarkers Predictive of Later Life Mortality. *PNAS*, 2006; 103 (38): 14158-14162.

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## HGB A1C VS GLUCOSE

- Glucose = snap shot; HgbA1C = 3 month average
- White coat hyperglycemia
- Anti-insulin antibodies
- Glucose / Insulin ratio

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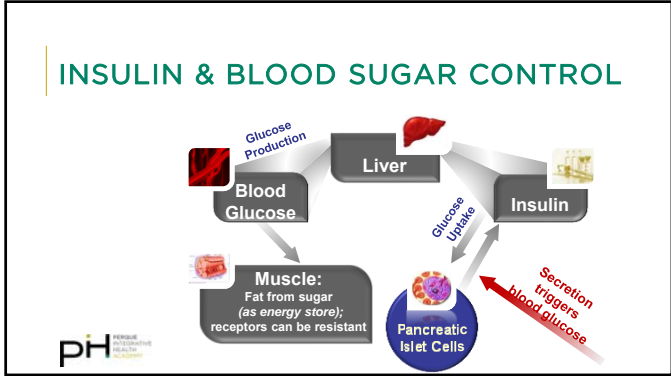
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### CHRONIC INFLAMMATION = CHRONIC DISEASE = CHRONIC REPAIR DEFICIT (CONT'D)

2015 US:  
40 MM diabetics  
100 MM pre-diabetics

By 2025:  
65 MM Diabetics &  
130 MM pre-diabetics

The slide includes two book covers: "THE SECRET KILLER" by Dr. Mark P. Mattar and "Chronic Inflammation: The Hidden Link Between Obesity, Diabetes, and Metabolic Syndrome" by Dr. Mark P. Mattar. The PH logo is in the bottom left.

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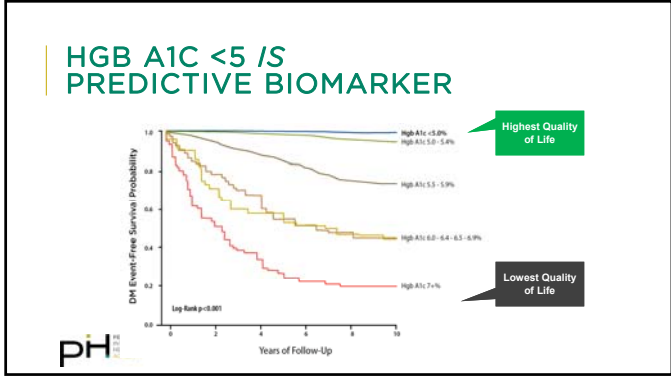
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## GLUCOSE REGULATION

Fasting **Insulin**: lower half of lab range  
**C-Reactive Protein (hsCRP)**: <0.5  
**HbA1C (Hgb A1c)**: <5%  
**Insulin Resistance**: HOMA, G/I ratio, Hgb A1c, anti-insulin antibodies, rT3

**Fructosamine**: altered by hypothyroid / hyperthyroid regulation.

PH PERQUE INTEGRATIVE HEALTH ACADEMY  
 Udozsa SV, Manjrekar PA, Udozsa VA, Vivian D. Altered fructosamine and lipid fractions in subclinical hypothyroidism. *J Clin Diagn Res.* 2013;7(1):18-22. doi:10.7860/JCDR/2012/5011.2660

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## hsCRP <0.5 / IS PREDICTIVE BIOMARKER

Calculated Framingham 10-Year Risk

PH PERQUE INTEGRATIVE HEALTH ACADEMY  
 Ridker PM, Wilson PWF, Grundy SM. *Circulation* 2004; 109: 2818-2825

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## hsCRP MEASURES REPAIR NEED

**Inflammation** in pathology = **Repair deficit** in physiology  
 Healthy body repairs w/o **hsCRP** ... 'cry for help'

PH PERQUE INTEGRATIVE HEALTH ACADEMY  
 Vavuranakis M, Kariori MG, Kalogeris KI, Vrachatis DA, Moldovan C, Tousoulis D, Stefanadis C. Biomarkers as a Guide of Medical Treatment in Cardiovascular Diseases. *Curr Med Chem.* 2012; 19(16): 2485-2496.  
 Silha D, Pais de Lacerda A. High-sensitivity C-Reactive Protein as a Biomarker of Risk in Coronary Artery Disease. *Rev Port Cardiol.* 2012; 31: 733-745.  
 Jaffe R, Mani J. Rethink Health: Inflammation is Actually Repair Deficit: Using Physiology First to Achieve Better Outcomes, Part 1: Value and Importance of Understanding Inflammation as Repair Deficit. *Townsend Letter for Doctors and Patients.* 2013, Jun 15(9): 68-74.

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## HOMOCYSTEINE 6MMOL/L IS PREDICTIVE BIOMARKER

Nygård O, Nordrehaug JE, Refsum H, Ueland PM, Farstad M, Vollset SE. Plasma Homocysteine Levels and Mortality in Patients with Coronary Artery Disease. *NEJM*. 1997; 337(4): 230-236.

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## HEALTHY METHYLATION: B COMPLEX, C

**Difference in Five-Year Mortality Risk**

Relative Risk at Different Homocysteine Levels

**Difference in Senility Risk**

Relative Risk of Senility in Relation to Homocysteine Levels

Methylation cofactors delivered in lingual dots

Arch Gen Intern Med. 2004; 160: 3-32. Arch Intern Med 2003; 163: 1933-1937. NEJM. 2002; 346: 476-483. Schroecksnadel K, et al. Hyperhomocysteinemia & Immune Activation. *Clin Chem Lab Med* 2003; 41(11):1438-1443.

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## HOMOCYSTEINE < 6MMOL/L IS GOAL

### LIFELY COLORS: CAROTENOIDS & B COMPLEX

**Targeted Supplementation**

**For healthy methylation**

- Vitamin B12 (hydroxocobalamin)
- B6
- Mixed natural folates

Lingual dot for optimum uptake

**Comprehensive antioxidants**

- Pure silymarin
- CoQ10
- Mixed natural carotenoids
- Mixed natural tocopherols

Micellized in a softgel for increased uptake

Chew B P, Park J S. Carotenoid Action on the Immune Response. *J Nutr*. 2004 Jan; 134(1): 257S-261S.  
 D'Adamo C R, Miller R R et al. Higher Serum Concentrations of Dietary Antioxidants are Associated with Lower Levels of Inflammatory Biomarkers During the Year After Hip Fracture. *Clin Nutr*. 2012 Oct; 31(6): 659-665  
 Brady J, Holford P. Homocysteine Revisited the H Factor Solution. BHP, N Bergen, NJ, 2003  
 Jaffe R, Mani J. Clinical Evidence in favor of specific polyphenolics. In: Watson RR, Preedy VR, Zibadi S, Eds. *Polyphenols in Human Health and Disease*, Academic Press, 013, 696-705.

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**HOMOCYSTEINE  
BIODETOX SUPER FOODS**

Garlic, ginger, onions, broccoli sprouts, eggs

**GGOBE**, Sulforaphane, IP6, minerals



Glutamine recycled by **PAK** cell energy repair

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Jaffe, R. Diabetes as an Immune Dysfunction Syndrome. In: Watson RR, Preedy VR, Eds. Bioactive Food as Dietary Interventions for Diabetes, Academic Press, 2013, 41-52.

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**FUNCTIONAL IMMUNOLOGY**

- Immune system = amplified response to foreigners
- Inflammation = repair deficit; toxin / immunotoxin load
- Delayed allergies require cell culture ex vivo Lymphocyte Response tests to distinguish helpful from harmful defenses
- Comprehensive detoxification & immune repair:
  - Eat, Drink, Think, Do
  - Personalized lifestyle repair
- Proactive primary prevention in practice

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**LRA TESTS CLINICALLY  
INDICATED FOR ALL...**

Autoimmune conditions

Chronic inflammatory conditions

Chronic degenerative conditions

Distinguish immune tolerance & intolerance

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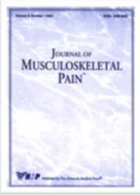
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**MULTIPLE SUCCESSFUL OUTCOME STUDIES**

"A Novel Treatment for Fibromyalgia Improves Clinical Outcomes in a Community-Based Study"

- 50% less pain
- 70% less depression
- 50% more energy
- 30% less stiffness



**PH** PERQUE INTEGRATIVE HEALTH ACADEMY  
Jaffe RM, Deuster PA. A Novel Treatment of Fibromyalgia Improves Clinical Outcomes in a Community-Based Study. *Journal of Musculoskeletal Pain*, Vol. 6, No. 2.

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**Multiple Successful Outcome Studies**

CLINICALLY SUBSTANTIATED IN DIABETES OUTCOMES

After just 6 months of implementing the recommendations following their LRA tests, diabetic participants showed:

- 1mg% ↓ in Hgb A1c in both groups (from best standard of care)
- 46% improvement in Type 1
- 18% ↓ in insulin in Type 2
- 13% ↓ in HbA1C levels in Type 2



**PH** PERQUE INTEGRATIVE HEALTH ACADEMY  
Jaffe R, Mani J, DeVane J, Mani H. Tolerance loss in diabetics: Association with foreign antigen exposure. *Diabetic Medicine: - A Journal of the British Diabetic Association* 2006 Aug;23(8): 924-5.

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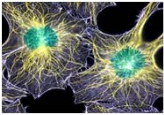

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**1ST AM UR PH AS PREDICTIVE BIOMARKER**

- Status: cell acids & minerals
- Enzyme catalysts pH sensitive
- Protein efficiency >90+% or <10%
- Mg<sup>++</sup> forgotten electrolyte
  - Mg uptake enhanced w/ Choline Citrate: 440-880+ mg/d elemental Mg<sup>++</sup>

**PH** PERQUE INTEGRATIVE HEALTH ACADEMY  
Jaffe R. The Alkaline Way in Digestive Health. In: Watson RR, Preedy VR, Eds. *Bioactive Food as Dietary Interventions in Liver and Gastrointestinal Disease*. Academic Press, 2013, 1-21.

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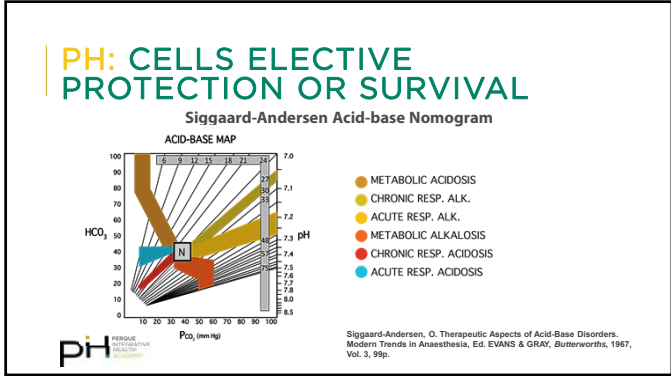
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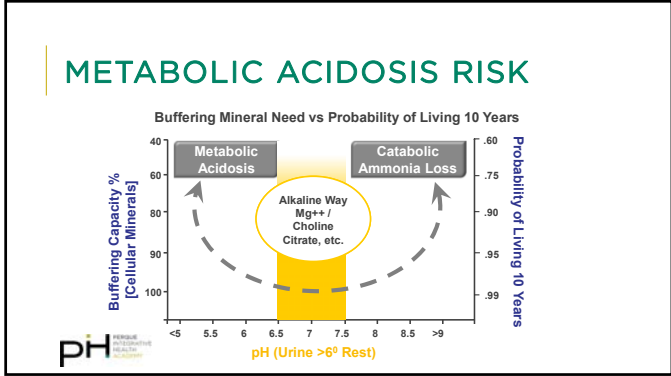
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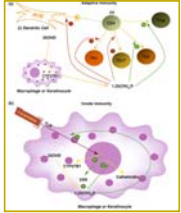
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## VITAMIN D IS PRIMARY BIOMARKER



Liver & Kidney hydroxylate  
adhesion molecule between cells

Communicates enough is enough

Bone, vessel, & brain health

Anti-cancer surveillance  
40+ MM poorly absorb D... mucosal uptake!

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Health Studies Collegium

Jorge N. Artaza, Rajnish Meetrota, Keith C. Norris. Vitamin D and the Cardiovascular System. *CJASN* Sep 2009; 4 (9) 1515-1522

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## VITAMIN D3 (CHOLECALCIFEROL)

Why goal value for 25 (OH)D– 50-80 ng/ml

- Maternal status: antirachitic activity in breast milk occurs at 45 ng/ml or higher
- Parathyroid hormone is maximally suppressed at >40 ng/ml; avoids hyperparathyroidism especially in impaired kidney functions
- Consistent sun exposure in the 21<sup>st</sup> century is not easily achieved

**25 (OH)D level of 150 ng/ml: lower limit of toxicity.**

• Vieth, R, Y Lada, and PG Wallich. "Age-related changes in the 25-hydroxyvitamin D versus parathyroid hormone relationship suggest a different reason why older adults require more vitamin D." *Journal of Clinical Endocrinology and Metabolism*, 2003.

• Wegner, CL, TG Halsey, D Fleming, M Ebeling, and BW Hollis. "High-Dose Vitamin D3 Supplementation in a Cohort of Breastfeeding Mothers and Their Infants: A 6-Month Follow-Up Pilot Study." *Breastfeeding Medicine*, 2006.

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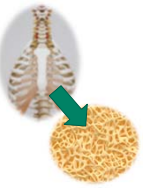
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## VITAMIN D3 (CHOLECALCIFEROL)



- Enhances absorption of minerals in the gut
- Helps mobilize calcium from bones into the bloodstream when intake is low
- Regulates synthesis of Gla-protein osteocalcin by osteoblasts responsible for making sure calcium is deposited in new bones.

Goal value for Vitamin D – 50-80 ng/ml

• Lanham-New SA. Importance of calcium, vitamin D and vitamin K for osteoporosis prevention and treatment. *Proc Nutr Soc*. 2008 May;67(2):163-176.

• Okano T. Gla-containing proteins. *Clin Calcium*. 2014 Feb; 24(2):241-248.

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## OMEGA -3 INDEX



**High Omega 6/3 ratio**

- Increased inflammation
- Immune imbalance
- Th1 Th2 diseases

William Harris, Ph.D.,  
1985 to today

**PH** PERQUE INTEGRATIVE HEALTH ACADEMY

Simopoulos AP. The importance of the ratio of omega-6/omega-3 essential fatty acids. *Biomed Pharmacother*. 2002 Oct;56(8):365-79.  
Harris WS and von Schacky C. The Omega-3 Index: A New Risk Factor for Death from CHD? *Preventive Medicine* 2004;38:212-220.

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## ESSENTIAL FATTY ACIDS

**High Omega 6/3 ratio**

- Increased inflammation
- Immune imbalance
- Th1 Th2 diseases

**Omega 3 fats:**

- Improve mitochondria-related redox status.
- Reduce triglycerides, LDL-C
- Reduce incidence of MI

**PH** PERQUE INTEGRATIVE HEALTH ACADEMY

• Simopoulos AP. The importance of the ratio of omega-6/omega-3 essential fatty acids. *Biomed Pharmacother*. 2002 Oct;56(8):365-79.  
• Olivera MR, Nabavi SY, Nabavi SM, Jardim FR. Omega-3 polyunsaturated fatty acids and mitochondria, back to the future. *Trends in Food Science & Technology*. Volume 67, September 2017, Pages 76-92.  
• Manson JE, Cook NR, Maize M. n-3 Fatty Acids and Prevention of Cardiovascular Disease and Cancer. *N Engl J Med* 2019; 380:23-32 Disease and Cancer

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## ESSENTIAL FATTY ACIDS

Why hs Omega 3 index

- Omega-3 fatty acids - whole blood, whole plasma, plasma phospholipids : confounding results
- EPA + DHA in erythrocyte fatty acids defined as omega 3 index in 2004
- Renamed **hs-Omega-3 Index**: more precise method
- Only standardized analytical procedure used now.
- Provides clearer picture of the effects of EPA + DHA.

**PH** PERQUE INTEGRATIVE HEALTH ACADEMY

• Harris WS, von Schacky C, Park Y. Standardizing Methods for Assessing Omega-3 Biostatus. In: Mohtarama RK, editor. *The Omega-3 Deficiency Syndrome*. Nova Publishers; Hauppauge, NY, USA; 2013. pp. 385-398.  
• Harris WS and von Schacky C. The Omega-3 Index: A New Risk Factor for Death from CHD? *Preventive Medicine* 2004;38:212-220.  
• von Schacky C. Omega-3 index and cardiovascular health. *Nutrients*. 2014;6(2):1799-814.

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## OMEGA 3 INDEX >8% GOAL VALUE

SAMPLE RESULT **Omega-3 Index® = 16.4%**

Reference Range\*: 0.5% = 10.6%

Your **Omega-3 Index** is within the target range.  
You are advised to maintain your current intake of omega-3 fatty acids.

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\* Harris WS and von Schacky C. The Omega-3 Index: A New Risk Factor for Death from CHD? *Preventive Medicine* 2004;39:212-220.

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## HS OMEGA 3 INDEX

**HS-Omega-3 Index® = 16.4%**

Reference Range\*: 0.5% = 10.6%

**Omega 3 Index**  
Goal: 8%

Your **HS-Omega-3 Index** is within the target range. You are advised to maintain your current intake of omega-3 fatty acids.

Fatty Acids Ratio	
Omega-6:Omega-3	(0.0 – 14.9)* 1.3

Omega 6: **Omega 3** Ratio Goal: 1

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## ESSENTIAL FATTY ACIDS

### Healthy fats

- Oils: organic coconut, green cloudy EVOO, ghee, grapeseed, almond
- Eggs, nuts/seeds
- Whole fish from deep cold water or wild, line-caught fish e.g. salmon.
- **EPA+DHA**: distilled under N<sub>2</sub>; 2-10 gm /day

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Liu AG, Ford NA, Hu FB, Zelman KM, Mozaffarian D, Kris-Etherton PM. A healthy approach to dietary fats: understanding the science and taking action to reduce consumer confusion. *Nutr J*. 2017;16(1):53. PHA/CD/EMF 42

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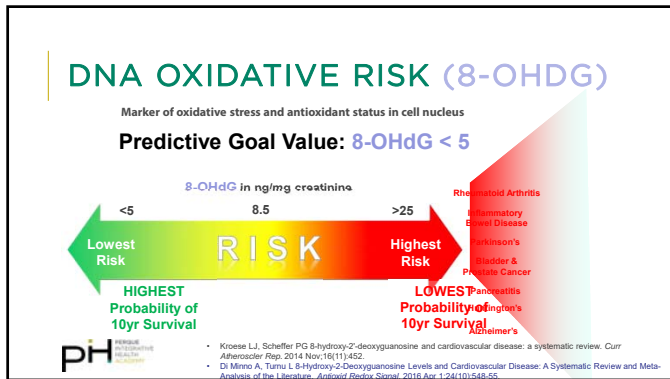
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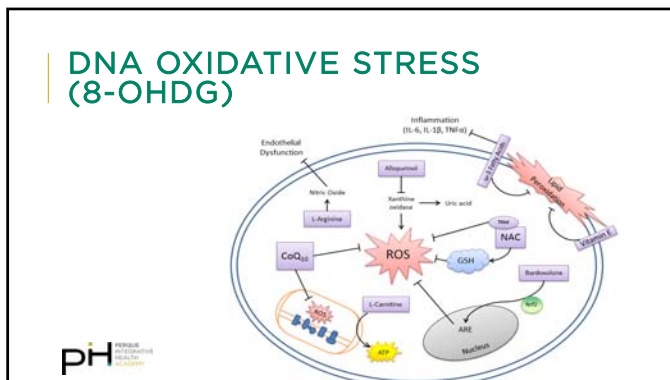
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### PREDICTIVE BIOMARKERS

**Why these specific epigenetic tests**

- Based on **biochemical individuality** (Roger Williams)
- Bring health improvements + clinical changes within **months** (Cheraskin, Ringsdorf, Hoffer, Osmond & Pfeiffer)
- High sensitivity PB w/ variance of <5% are more **predictive**
- Predictive goal values = best outcome for **individual**
- Epigenetics covers 92%; genetics covers 8% of lifetime health

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 INTEGRATIVE HEALTH ACADEMY

Donald Fredrickson, "Task Force on Genetic Factors in Atherosclerotic Disease, National Heart and Lung Institute, 1974-1978 [subseries]."  
 Report from the National Heart and Lung Institute, 1974-1978.  
 JB Stanbury, JB Wyngaarden, DS Fredrickson, eds., *The Metabolic Basis of Inherited Disease* (New York, Toronto, and London: McGraw-Hill, 1960).

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## VALUES: 'NORMAL' VS PREDICTIVE GOAL

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Homocysteine	4-17 µmoles/L	<6 µmoles/L
LRA	NA	Immune Tolerance
1 <sup>st</sup> AM urine pH	4.6-8	6.5-7.5
Vitamin D	20-40 ng/mL	50-80 ng/mL
Omega 3 index	ND	>8%
8 OH dGuanosine	4.6-19.2 ng/mg (11.9+/-7.3 ng/mg)	<5ng/mg creatinine

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## BIOMARKER VS. PREDICTIVE BIOMARKER

**Biomarker**

a portmanteau of "biological marker", refers to a broad subcategory of medical signs – i.e., *objective indications of medical state observed from outside the patient – which can be measured accurately and reproducibly.*

**Predictive Biomarker**

A "**predictive** biological marker" is a specific subcategory of analytic observations, i.e., *objective indications of medical state observed from outside the patient that can be measured accurately and reproducibly while predicting 10 year survival & QoLY.*

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Kyle Strimbu & Jorge A. Tavel, MD. What are Biomarkers? *Curr Opin HIV AIDS*. 2010; 5(6): 463-466.

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## AVERAGES DECEIVE; INDIVIDUALS CHOOSE

**PH** PERQUE INTEGRATIVE HEALTH ACADEMY

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**HIGH SENSITIVITY PREDICTIVE BIOMARKERS (HSPB) PERSONALIZED, EVIDENCE-BASED, COMPARATIVE**

**hsHgb A1c:** Sugar, insulin... AGEs

**hsCRP:** Inflammation, repair disease

**8 oxo-guanine:** Oxidative stress... ALEs

**hsHomocystei:** Methylation, detox... Sulfur

**Omega 3:** Omega 3:6; EFAs

**hsLRA:** Immune Tolerance

**Vitamin D:** Cell talk & adhesion

**1st AM urine pH:** cell acidosis risk

Jaffe R. Predictive Biomarkers Provide Evidence for Comparative Effectiveness Research. HSC 90\_13-01 Advisory on Predictive Medicine & Health Promotion. Gruenewald TL, Seeman TE, Ryff CD, Karlamangla A, Singer BH. Combinations of Biomarkers Predictive of Later Life Mortality. PNAS. 2006; 103 (26): 14150-14152.

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**PREDICTIVE BIOMARKERS (PB) FOR PROACTIVE, PERSONALIZED CLINICAL CARE**

**PB tests & functional assessments** include all **epigenetic risks**

**Least risk-highest gain** goal values *rather* than **normal** lab values

**High sensitivity predictive biomarkers** = personalized and higher quality clinical care.

**Individualized** supplementation based on **predictive biomarkers**

**Let's Rethink Health together!**

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**PREDICTIVE BIOMARKERS** | **RUSSELL JAFFE MD, PhD,CCN**

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