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Dear Dr. Garry F. Gordon,

Your recent visit to American Metabolic Laboratories was a very pleasant surprise.

As a follow up and in line with your request, I would like to give you a brief description of the Cancer Profile© or CA Profile©. As you know, the tumor markers used are the HCG hormone tests, PHI enzyme kinetic test, and the broad spectrum cancer marker CEA. Also included are TSH, GGTP and DHEA-S. Altogether there are eight clinical laboratory determinations.

The enzyme**, Phosphohexose Isomerase (PHI)**, aka. Glucose Phosphate Isomerase or Phosphoglucose Isomerase is a regulatory catalyst of anaerobic sugar metabolism (Embden-Meyerhof glycolitic and glucogenetic pathways) by reversibly converting glucose-6-phosphate to fructose-6-phosphate. In the past it was reported by various authors that this protein is the autocrine motility factor or AMF. As such, it stimulates cell motility in an autocrine manner and it is closely related to malignancy. This multi functional enzyme is also known as a neuroleukin. PHI was originally purified from a human melanoma cell line. It was observed that this neuroleukin, a cytokine, stimulated random or direct motility of cells in an autocrine manner. Initially PHI was found to be elevated in patients with malignant tumors such as gastrointestinal, kidney, breast, colorectal and lung. Specific enzyme inhibitors inhibit PHI enzyme activity as well as motility stimulation.

Some other mechanisms that the AMF plays a role in:

1) small GTPase of the Rho family controlled cell growth, morphogenesis, cell motility, cytokinesis, trafficking and organization of cell cytoskeleton, cell motility, transformation and metastasis
2) effect on endothelial cells, i.e. angiogenesis promotion
3) involvement in the accumulation of ascites fluid
4) anti-apoptotic effect

For References see,

REVIEW
T. Ynagava, et al.,Novel roles of the autocrine motility factor/phosphoglucose isomerase (PGI or PHI) in tumor malignancy, Endocrine-Related Cancer 11 (4) 749 – 759 (99 references)

The PHI enzyme and HCG hormone tests have been successfully implemented and perfected, by Dr. Schandl, as tumor markers in a licensed laboratory in the State of Florida that is both CLIA and COLA certified since 1978.

The **HCG** hormone has been accepted in clinical laboratories as an established tumor marker for germinal tumors. However, volumes of biomedical literature have convincingly established the fact that it is an excellent cancer indicator for most if not all types of cancers.
Acavedo, H.F., et al. used 85 different cancer cell lines of different types and origins from American Type Culture. They described the expression of complete HCG in cell membranes in association with metastatic aggressiveness of tumors of different histological types and origin. However, the expression of intact HCG was absent in cells of nonmembrane tissue or benign neoplasms. These researchers maintained that synthesis and expression of HCG, its subunits, and its fragments is a common biochemical denominator of cancer. They found translatable HCG-ß mRNA in all the tested fetal and cancer cell lines. In fact, detectable levels of HCG were reported by the authors in the blood and urine in cancers of the breast, bladder, gastrointestinal tract, lung, melanoma, and embryonal carcinomas.

Acavedo, H.F., et al. Flow Cytometry Method for the Analysis of Membrane-Associated HCG, Its Subunits and Fragments on Human Cancer Cells. Cancer. 1992; 69:1818-1828.

Ibid, HCG-ß Gene Expression in Cultured Human Fetal and Cancer Cells. Cancer. 1995; 76:1467-1475.

HCG-ß was detected in the serum samples of patients with a variety of nontrophoblastic tumors and the presence of the hormone was highly indicative of a malignant diagnosis and aggressive tumors of the lung, pancreas and liver.

Marcillac, I., et al., Free Human HCG –ß in Gonadal and Nongonadal Neoplasms. Cancer Res., 1992; 52:3901-3907.

Clinical laboratory evidence obtained by performing ultra sensitive HCG tests at American Metabolic Laboratories indicates that HCG may be present in any and all types of cancers. It is notable that the HCG hormone and the PHI enzyme have a sign co-sign relationship, meaning while one can be elevated and the other one normal, the next set of tests results could have the two switched. The Cancer Profile© detects metabolic changes when used in its entirety. Therefore, ordering the complete Cancer Profile© for early detection or follow-up cases is highly recommended.

American Metabolic Laboratories is offering two, different types of HCG hormone tests within the Cancer Profile© and Longevity Profile©.

Recently, **Urine HCG** test was added for those patients, who have a history of protracted exposure to domestic animals and in very rare occasions have developed heterophile antibodies in their blood serum. The consequence could be false positive results for the HCG hormone.

HCG Tests Performed at American Metabolic Laboratories:

1) HCG-IRMA, done by super sensitive radioimmunometric assay
2) HCG-IMM, done by chemiluminescence
3) HCG-Urine-Quantitative test by chemiluminescence

(American Metabolic Labortatories may be the only laboratory in the USA and elsewhere offering quantitative urine HCG test with excellent accuracy, precision and linearity.)

The IRMA and the IMM are two dissimilar, confirmatory methods for the ascertainment of accuracy of the test results.

John Beard (1858 – 1924) proposed, the Thropoblastic Theory of Cancer, The Lancet, 1902. According to Dr. Beard's postulate, the origin of all cancers may be the embryonic cell, TROPHOBLAST. One of the major functions of these embryonic cells is to produce HCG, the pregnancy hormone. Trophoblast cells have been identified in numerous cancerous tissues.

Dr. Schandl named HCG the pregnancy and malignancy hormone.

Martinez Flores, et al., Development and Validation of an in vitro Culture Model for the Study of the Differentiation of Human Trophoblast. Ginecol Obstet Mex. 2006 Dec: 74(12):657-65.

Bjurlin MA, et al., Histologically Pure Seminoma with an Elevated beta-HCG of 4497 IU/L. Urology. 2007 Nov; 70(5):1007. e13-5.

Some researchers have described the infrequent, very low level presence of pituitary HCG-like substance in older female patients. The molecule they call pituitary HCG has an N-linked sugar side chain resembling that of LH rather than HCG. Hence the term HCG-like came into use. However, there seems to be no evidence that this molecule is actually made in the pituitary gland. The researchers have postulated that GRH (gonadothropin releasing hormone) is stimulating the production of LH, FSH, and also HCG. Pituitary production of HCG was reported to be suppressed by high does of oral progesterone treatment for 1- 3 weeks. The disappearance of HCG after treatment will rule out the presence of tumor generated HCG. (May bioidentical HRT be feasible for asymptomatic, LH and FSH elevated women/men in order to suppress HCG production?)

Birken S., et al., Isolation and Characterization of Human Pituitary Chorionic Gonadotropin. Endocrinol 1996; 137:1402-11.

Stenman UH., et al., Serum Levels of HCG in Non-Pregnant Women and Men are Modulated by GRH and Sex Steroids. J Clin Endocrinol Metab 1987; 64:730-6.

It must be noted that the above studies did not take in consideration the overall metabolic effect of the HCG hormone. The fact remains if it is present in the serum it will exert stimulating, metabolic, regulatory, growth and cell proliferation promoting functions in target organs. HCG, the pregnancy/malignancy hormone has the propensity to initiate/stimulate RNA, DNA and protein synthesis. Similarly to the PHI enzyme, it is produced under anaerobic conditions, yet it is a potent immune-inhibitor and angiogenesis promoter.

The presence of any quantity of HCG, other than in pregnancy, can potentially herald and contribute to the development and progress of any type of cancer.

GGTP is a constituent of the profile(s) for monitoring hepatic, renal, cardiac organ/tissue health.

CEA is a broad spectrum tumor marker that may detect or monitor most malignant processes.

TSH governs the thyroid's basic metabolic rate function, i.e. rate of oxidative phosphorilation. Hypothyroid condition may usher in anaerobic glucose fermentation leading to cancer. Also, cancer therapies may evoke hypothyroidism.

Smith G L, et al. Risk of Hypothyroidism in Older Breast Cancer Patients Treated with Radiation, Cancer. 2008 Mar 15; 112(6):1371-9.

Madanat L M, et al. Hypothyroidism among Pediatric Cancer Patients, Int J Cancer. 2008 Apr 15; 122(8):1868-72.

DHEA – the adrenal anti-stress, pro-immunity, longevity hormone. Studies conducted by Dr. Schandl indicated that most, if not all cancer patients presented with low DHEA levels. Often, 40 years old individuals showed DHEA quantities of 80-90 year old patients' values. The importance of this steroid hormone in cancer prevention and therapy cannot be over emphasized. See,

Oberbeck R, et al. Dehydroepiandrosterone: A Modulator of Cellular Immunity and Heat Shock Protein 70 Production During Polymicrobial Sepsis, Intensive Care Med. 2007 Dec; 33(12):2207-13. Epub 2007 Sep 26.

Rook GA, Baker R, Zumla A. Steroid Metabolism and Immunity: Therapeutic Implications. BioDrugs. 1997 Sep; 8(3):157-63.

CLINICAL LABORATORY REPORTS:

Schandl, E.K., Clinical Biochemical Parameters in Cancer Diagnosis and Therapy, 1980. Clinical Chemistry, 26 1040.

von E.K. Schandl, Klinish Biochemische Parameter bei Krebs, 1981. In Die Praxis der Zelltherapie, p.98, Medizinish Literarische Verlagsgesellschaft mbh, Uelzen.

Von Schandl, in Onkologischer Dialog, Sontag,16 Juni, 1991. Ed. Dr. Hasso H. Thalmann, Angelos N. Sagredos, bei Onkologischen Erkrankungen.

Schandl, E.K., The Cancer Profile, 2004 American Association of Bioanalysts Educational Conference, Las Vegas, NV. Poster Presentation.

Schandl, E.K., Carlo,Allison, Schandl, C.A. Cancer Profile v. CA 15.3, 2006. American Associates of Bioanalysts, 50th Anniversary – Award winning poster presentation, Las Vegas, NV.

Schandl, E.K., Carlo, Allison, Schandl, V.A. The Cancer Profile v. CEA Tumor Marker in Breast Cancer Patients, 2007. American Association of Bioanalysts, 51st Annual Meeting and Educational Conference, Orlando, FL. Oral and Poster Presentation.

The **Longevity Profile**©, that does include the Cancer Profile©, is presently the most thorough clinical laboratory biochemical workup of an individual patient. For rational and the tests included, see http://caprofile.net .

ABSTRACT:

The *Cancer Profile*© *(CA Profile©)* has been designed as an adjunct diagnostic tool for early cancer detection and follow-up. The components of the *CA Profile* are HCG total, HCG-ß, ß fragments and core fragments, PHI enzyme (phosphohexose isomerase or glucose phosphate isomerase), and CEA tumor markers, and GGTP, TSH, DHEA-S. HCG is the pregnancy/malignancy embryogenic hormone, PHI regulates cellular anaerobic metabolism and it is the *autocrine motility factor* (*AMF* /malignancy factor). DHEA-S is the adrenal anti-stress, pro immunity, and longevity hormone. These latter three analytes are only peripherally related to cancer and are not tumor markers. However, a low adrenal DHEA or low thyroid activity can predispose to cancer, whereas the GGTP test is necessary for monitoring hepatocellular integrity.
It was found that in pathologically established cases in 240 *lung cancer* patients 221, i.e. 92% gave positive tumor marker results. In *breast cancer*, again 240 patients yielded 221 positives, i.e. 92% of all the individuals. Of 59 *colon cancer* cases 55, i.e. 93% were positive. The overall performance of the *CA Profile* in established malignancies of all sites was 89% where n = 636. It is to be noted, however, that the CA Profile is not organ or site specific. It will warn of biochemical imbalances characteristics of either a developing or existing malignant neoplasm.
Interestingly, preliminary data indicated that from the apparently normal, disease free population 68% females (n=53, all ages, all locations USA) had abnormal CA Profile results, and 66% demonstrated elevated coronary risk factors, such as HOMOCYSTEINE, Hs-CRP, LDL. Similarly, 56% of the male population tested (n=50) presented with elevated *CA Profile*, and 74% had abnormal coronary risk factors. The ***CA Profile***© HOMOCYSTEINE, hs-CRP, LDL are some of the constituents of the ***Longevity Profile***©.

The *CA Profile* was found to be an excellent adjunct tool for early detection of malignancies by producing abnormal clinical laboratory results, sometimes several years prior to actual diagnosis by current high technology methods. The *Cancer Profile also* proved to be of great value in monitoring the progress of cancer patients.

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Respectfully yours, Emil