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Increased Serum Level of RPMPS-1/S27 Protein in Patients with Various Types of Cancer Is Useful for the Early Detection, Prevention and Therapy

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Abstract. *Background: When a protein has a useful and unique function, the selective pressures of evolution conserve the DNA sequences encoding such proteins; the conservation of these domains may have pragmatic use in better understanding viral and spontaneous carcinogenesis in eukaryotic cells. The unique functions of ribosomal protein (RP) Metallopanstimulin-1 (MPS-1/RPS27), and a few other RPs, in growth regulation and carcinogenesis (chemical, viral, radiation and chemotherapy-induced) could be used for the early detection of cancer using serum, or in follow-up therapy. Materials and Methods: The MPS-1 serum test was performed in the serum of patients by radioimmunoassay using specific antibodies directed against the N-terminus (amino acids 2 to 17; synthetic peptide) of MPS-1 according to previously described procedures (Fernandez-Pol, JA, 1994). Results: The data presented here indicate that antibodies to MPS-1 detect a zinc finger protein of Mr 9.8 kDa identified by MS and sequencing as MPS-1 in patients having various types of cancer. MPS-1 increases with aggressivity of cancer, irrespective of the cancer types studied in this work. In healthy individuals of the same age range, the levels of MPS-1 increase slowly and progressively at less than 1% per year as the patients age. Conclusion: The MPS-1 test may be useful as an aid in: i) early detection of a wide variety of cancer types; and ii) the prognosis and management of cancer patients by following the changes in the concentrations of MPS-1 in serum. Moreover, the results suggest that the combined use of MPS-1 with physical methods of cancer detection such as positron emission tomography, computer assisted tomography, or magnetic resonance imaging techniques may significantly improve the chances of identifying an active tumor in early stages by serodiagnosis of MPS-1. In patients having other diseases (such as rheumatoid arthritis, which manifests as a proliferative disease) or in healthy individuals having no evidence of disease, the identification of as yet unrecognized active oncogenesis, may be significantly improved by using MPS-1. The data on genome context analysis indicates that the presence of MPS-1 in the blood is an indicator of oncogenesis. Thus, the test may be used to help prolong the life of the patients, if the cancer is detected early.*

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Metallopanstimulin-1 (MPS-1) is a ribosomal protein (RP) S27, and thus also denoted in gene banks as RPMPS-1/S27 (which is the intracellular form). MPS-1, (which is the extracellular form present in the serum), is a 9.8-kDa subunit zinc finger protein which is expressed in a wide variety of actively proliferating normal cells and in aggressive malignant neoplastic tissues (1-9). Experimental translation from basic science research to clinical science and important milestones in the characterization of this multifunctional protein are briefly described in Table I, which refers to experiments performed in the laboratories of Fernandez-Pol, from 1989 until 1999. An important finding of MPS-1 in gastric cancer progression and carcinogenicity is that of Yun-wei *et al*. (10). A remarkable recent finding is that of Xiong *et al*. indicating that ribosomal protein RPMPS-1/S27 and S27-like interplay with the p53-MDM2-axis as a target and regulator of oncogene expression (11). The authors believe that the data indicates that the chances of eradicating cancer in general are significantly higher than previously thought, as new targets that regulate DNA repair have been recently identified (6, 8, 11, 12).

RPMPS-1/S27 is a ribosomal protein that is over-expressed in many cancer cell lines, in most cancer tissue biopsies, and is increased in the serum of patients with early stage cancer (8). Previous work by Fernandez-Pol with cancer cells utilizing gene cloning (1, 2, 8) and Berthon *et al*. (12) with Archaea utilizing genome context analysis,

Table I. *Translating basic research in the clinic: important milestone that lead to the development of the RPMPS-1/S27 test for the early detection of cancer in the human sera.*

1990.	Identification, Isolation and sequencing of a inducible growth factor denoted Metallopanstimulin-1 (RPMPS-1/S27) from breast cancer cells.
1991.	RPMPS-1/S27 encodes a multifunctional ribosomal protein with Zinc Finger structure.
1992a.	RPMPS-1/S27 is overexpressed in carcinogenesis processes in eukaryotic cells.
1992b.	Characterization of chemical and physical proprieties of recombinant RPMPS-1/S27 generated in a *Baculovirus Autographa Californica* virus system.
1993.	Isolation from human sera. Sequencing and mass spectrometry (MALDI-TOF) of RPMPS-1/S27 proteins.
1996.	Development of RPMPS-1/S27 serum protein as a novel tumor marker test for the early detection of various types of carcinogenic processes in patients.
1999.	Isolation and sequencing of 38 novel growth factor-induced genes from breast cancer cells.

showed that RPMS-1/S27 is involved in translation, transcription, DNA repair, and ribosomal biogenesis. In normal aging cells, the level of RPMPS-1/S27 decreases when the cells age and reach the senescent stage (13). Initially, its expression was found to be increased in transformed cells in tissue culture (8).

As a result of the over-expression of RPMPS-1/S27 (8), a derivative of this protein, denoted MPS-1, is released from the tissues into the blood stream where it can be detected in the sera by sensitive techniques (6, 8). Furthermore, Fernandez-Pol *et al*. (5) demonstrated the potential of MPS-1 as a tumor marker in the serum for numerous different types of cancer (5, 8). Elevated MPS-1 levels and derivatives thereof were identified in cancer patients with greater than 90% confidence limits (8). In healthy individuals, not having malignant neoplastic disease previously, the MPS-1 levels were <10 ng/mL (>99% of a random population from 20 to 70 years of age). In untreated cancer patients, the MPS-1 level ranged from 15 to 50 ng/mL and in stage M1b (metastasis to the bones) the MPS-1 levels were extremely high (>100 to 1000 ng/mL). In M1b patients that did not respond to therapy, the MPS-1 levels remained very high (>100 ng/mL). In those patients that went into remission after treatment, the MPS-1 levels were reduced by >50-70% at 2 months post-treatment. The converse is also true: when the level of MPS-1 increases it can be predicted with >95% accuracy that the tumor relapse, allowing the oncologist to treat the tumor earlier (9).

This suggests that the MPS-1 test may be useful as an aid in: i) the early detection of a wide variety of neoplastic conditions; and ii) for the prognosis and management of cancer patients by following the changes in the concentrations of MPS-1 in serum. It is germane to point out here that the results indicate that both the combined use of MPS-1 in serum with physical methods of cancer detection such as computer assisted tomography (CAT), positron emission tomography (PET), or magnetic resonance imaging (MRI), can significantly improve the chances of detecting active oncogenic processes in their earlier stages. Furthermore, in patients having other diseases (such as rheumatoid arthritis which manifests as a proliferative disease of abnormal synovial cells) or in healthy individuals having no evidence of cancer or other diseases, the use of MPS-1 measurement may significantly improve the probability of early detection of active carcinogenesis not previously recognized by other diagnostic techniques. Finally, early diagnosis of cancer using the MPS-1 test may be economically beneficial especially if the test is combined with physical techniques (CAT, PET, MRI).

Intracellular RPMPS-1/S27 participates in critical homeostatic mechanisms and, when altered by the carcinogenic process, is released into the extracellular space and from there into the serum as MPS-1 (5-9).

This paper presents a large number of measurements in more than 2500 individual patients with many types of common cancers. It was decided to present individual patients in a summarized form obtained from complete computerized clinical charts, so if the reader wishes he or she can carry out from simple to more complex statistics, to evaluate the consistency of the data. This can be easily done as the values correspond to individual measurements of samples. It is believed that MPS-1 serum protein is a sensitive and reliable marker of detecting proliferative diseases, including benign, and malignant tumors, and non-malignant proliferative diseases.

Materials and Methods

Patients. This retrospective study (Tables II to XIV) was carried out on different types of patient samples measured in duplicate. Diagnosis was based on detailed computerized clinical history, including laboratory information, pathological diagnosis with various staining procedures for oncogenes, radiological information (CAT, PET, MRI, and Ultrasound), staging of cancer, treatment plan, results, chemotherapy protocols, radiation therapy and surgical procedures. Tumor registry information was also available. This research adheres to the principles of the Declaration of Helsinki.

As shown in Tables II to XIV, the clinical study consisted of individuals separated into healthy individuals, and individuals with active cancer of different types. Other malignancies category reflects individuals, who had cancer with unknown origin. The mean age of the group was 70±10 years, with a range of 19 to 100 years.

Analysis of human blood samples. The majority of the specimens consisted of discarded samples obtained from the Laboratory of Virology and Immunology, DVA Medical Center JC, St Louis, MO, USA (DVA Med. Ctr.). The use of residual blood samples was approved by the Human Research Studies Subcommittee, DVA Medical Center, as "Research Exempt from IRB (Internal Review Board) Review", in accordance with the USA FDA regulations CFR-21. Other samples were controls purchased from various commercial reference laboratories such as Nichols, CA, USA, Sigma-Aldrich, (St, Louis, MO USA, or Bioclinical Partners, Boston, MA, USA, and also from healthy individual volunteers who signed the proper written consents as required by the IRB of the DVA Med. Ctr., St Louis, MO, USA.

The serum samples corresponding to both healthy females and females with breast cancer in different stages of progression (0 to IV) were purchased from reference laboratories (Bioclinical Partners, Boston, MA, USA, and Nichols Laboratories, San Juan Capistrano, CA, USA).

Preparation of reagents. The critical reagents used for the MPS-1 Radioimmunoassay (RIA) serum test, were all made in the Laboratory of Molecular Oncology (DVA Med. Ctr., St. Louis MO, USA) and consisted of human recombinant MPS-1 protein (as an MPS-1 RIA control), synthesized in our laboratory from plasmid STIH2 in a *Baculovirus* insect system (2). The polyclonal antibodies to recombinant MPS-1 were created in this laboratory in rabbits. The use of rabbits was approved by the R & D Committee and the animals were supervised by the Board Certified Veterinarians of the Animal Research facility. Affinity chromatography purified polyclonal antibodies were prepared, characterized and, verified for quality control according to methods described elsewhere (2). The standard of reference for the MPS-1 RIA test was the *Baculovirus-produced human MPS-1 recombinant protein* (2). The RIA MPS-1 test used the MPS-1 Peptide-N-terminus (AA 2-17) of MPS-1. The Peptide (AA-2-17) was synthesized by Fmoc chemistry and was used to generate antibodies to Peptide (AA-2-17) in rabbits. The synthesis was verified by electrospray Mass Spectrometry (Protein and Nucleic Acid Chemistry Laboratory, Washington University, St. Louis, MO USA). The antibody is directed towards a unique site on the MPS-1 molecule (AA 2-17). The polyclonal antibodies were purified by affinity chromatography.

Radioimmunoassay procedure. The RIA used in the present research is based on the following US patents by Fernandez-Pol: (i) DNA vector with isolated cDNA gene encoding Metallopanstimulin (MPS-1), US. Pat. No. 5,243,041; (ii) Method of preparing and activating samples for RIA and other test, US Pat. No. 5,668,016; and Method of determining biological substances elevated in the presence of cancer and other neoplasms, US Pat. 5,955,387. These patents are hereby incorporated by reference. These patents contain in full detail the following numerical data and analysis: Distribution of MPS-1 values in human serum, the essential materials and sources, the stability, controls, preparation of reagents and sources, specimen collection and preparation, and preparation of samples for RIA. The RIA procedure in full numerical detail is presented in US Pat. 5,668,016, including: special considerations, data, calculations and RIA standard curve, quality control, drift values, parallelism and immunological identity, recovery, expected values, false positive and false negative results in various biological conditions, serum protein/MPS-1 relationship, and false positives.

The effect of boiling time on the measurement of MPS-1 in healthy individual's serum and cancer patient's serum is shown in Figure 1. In healthy individuals the serum MPS-1 barely increases after boiling while the MPS-1 molecule in metastatic cancer patients show a peak at 3 minutes at 100˚C of about 1000 ng/mL of MPS-1, indicating the release of MPS-1 from a serum carrier protein of Mr 90 kDa.

Methods to evaluate apoptosis and MPS-1 indices in malignant cells of the skin to estimate the release of MPS-1 in adjacent tissues and into serum. To assess the relative frequency of MPS-1 expression in individual cells and apoptosis in cells, malignant melanoma of the skin was used due to its high production of MPS-1 protein. Immunohistochemistry of MPS-1 and tunnel methodology for estimation of apoptosis was carried out in x, y and z Cartesian coordinates using specific software to analyze the slides to enable the generation of 3D images utilizing the Jurassic Park, Silicon Valley Computer and the corresponding 3D programs.

Protocols for detecting MPS-1 staining and apoptosis in formalin fixed sections were previously described (14, 15). For apoptosis, slides were stained using a commercially available kit denoted *Frag El-Klenow DNA Fragmentation Detection Kit* from Oncogene Research Products, Cambridge, MA, USA. One of the characteristics of apoptotic cell death is specific fragmentation of DNA. The details of the method are described elsewhere (8).

Statistical analysis. The RIA MPS-1 assay was evaluated for sensitivity, specificity, positive predictive value, negative predicted value, diagnostic accuracy, and the cutoff index to identify the optimum threshold level and assess its efficacy in the diagnosis of neoplasia. Differences between groups were identified with the Chi-square test for contingency tables and for standard deviation (14, 15). $P<0.05$ was defined as being statistically significant. Processing was carried out using the statistical functions provided by Excel (Microsoft Corp.). Correlation between MPS-1 levels *versus* the presence or absence of proliferative conditions was done using scatter plots for different values of the sample (15), the USA FDA approved guidelines for RIA (14), evaluation of diagnostic tests (16), and the method of Sackett *et al*. (16, 17). Quality control for RIA standard curves was carried out by the classical RIA Levy-Jennis plots to verify ±SD and ±SE, to determined compliance of the measurements (5,14). Full numerical details of all the procedures denoted above are presented in US. Pat. No. 5,668,016 and US. Pat. No. 5,955,387, containing also in detail the sources of the materials used in RIA and of the instruments used.

Results

Performance characteristics of the RIA MPS-1 assay. The reliability of the MPS-1 RIA procedure was evaluated by examining the reproducibility of measurements on selected reference samples that represent the range of values most frequently found in human sera (2-500 ng/mL). The results

Table II. *Measurement of circulating MPS in sera of patients evaluated for cancer.*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
1	3.2	1.8	No tumor	Cannabis S. abuse, macrocytic anemia
2	328	3160	Metastatic P	PC poorly diff., M1b, treated strontium therapy for pain
3	0.1	0.2	No tumor	Serum routine analysis
4	351	93.4	Metastatic P	PC poorly diff., T3a, possible M1b
5	189	91	Metastatic P	PC poorly diff., M1b/NX, TURP, hormonal therapy
6	273	377	Metastatic P	PC poorly diff., M1abc, patient died 4 days after sample collection
7	15.4	112	Cancer P	Hyperplasia, adenocarcinoma, adenofibroma
8	8.1	210	Cancer P	PC well diff., T3a/M0, no treatment
9	54.4	99.1	Metastatic P	PC poorly diff., T3c/M1b, untreated
10	6.9	0.4	Unknown	Recurrent bronchiectasis with secondary hemoptysis
11	52.6	0.6	Metaplasia	Dislipidemia, esophagitis, metaplasia reactive to ulceration
12	96.2	1	Unknown	Diabetes mellitus, serum routine analysis
13	15	0.8	BPH	Prostatic hyperplasia, TURP
14	16	1.7	Cancer P	Adeno CA; T2; prostatectomy
15	24.4	1.1	Pre-malig.	Lung infiltrates, chronic; pleural thickening probably asbestos related
16	22.2	122	Cancer P	PC well diff., T1c, untreated, history of lung carcinoma, resected
17	483.6	1734	Metastatic P	PC poorly diff., M1b, N3, chemotherapy, radiation therapy, palliative
18	6.3	852	Metastatic P	PC poorly diff., TURP, M1b, hormonal therapy, remission
19	7	31	No tumor	Chronic obstructive pulmonary disease
20	1	18.3	Cancer P/T	PC well diff., T3, radiation therapy
21	33	3.1		Serum routine analysis
22	3	7	BPH	Prostatic hyperplasia, glandular, inflammatory, TURP
23	3.1	6.5	No tumor	Blood routine, normal patient
24	3.3	6.3	BPH	Prostatic hyperplasia, glandular, inflammatory, TURP
25	3.6	1.4	Cancer P/T	Chronic prostatitis with focal well diff. adenocarcinoma, TURP
26	3.1	0.9	No tumor	Verruca vulgaris, skin
27	5.2	0.2	Tumor	1.5 cm lesion in RL lung, rule out carcinoma, colon diverticulosis
28	18.2	225	Metastatic P	PC poorly diff., M1b, hormonal therapy
29	17.82	22	Unknown	Coronary artery disease, serum routine analysis
30	0.9	0.2	No tumor	Congestive heart failure, COPD, severe coronary arthery disease
31	7.35	1.2	No tumor	Cardiomyopathy, diabetes type II, reumatoid arthritis, artheriosclerosis
32	31.89	95.4	Metastatic P	PC poorly diff., M1b, post-radiation therapy for metastatic disease
33	407.85	1099	Metastatic P	PC poorly diff., M1abc, radiation, patient died 8 d after sample collection
34	3.45	46.7	Cancer P/T	PC poorly diff., T1c, identified by needle biopsy, TURP
35	123.3	62.4	Metastatic P	PC poorly diff., M1b
36	17.2	6.4	Unknown	Coronary atherosclerosis
37	1.5	1	No tumor	Congestive heart failure, hypertension, COPD, hypercholesterolemia
38	22	0.9	Unknown	Alcoholic hepatitis, heroin dependence, no malignancy found
39	46.2	2.9	Unknown	Acute pancreatitis secondary to alcohol abuse, no tumor found
40	1.1	0.6	No tumor	Aortic artheriosclerosis
41	0.7	0.4	No tumor	Diabetes, general osteorthritis
42	1.02	1.1	No tumor	Bladder carcinoma, treated 12 years ago, no evidence of disease
43	0.54	0.5	No tumor	Atrophic gastritis, gastroesophageal reflux
44	1.6	1	No tumor	Hypertension
45	4.6	68.2	Cancer P/T	PC moderately diff, T3/M0, TURP, hormonal therapy
46	32.5	110	Metastatic P	PC poorly diff., T4a/M1ab
47	37	337	Metastatic P	PC moderaterly diff., T3c/M1ab
48	13.8	0.6	Cancer R	Post-right nephrectomy for renal cancer with possible metastasis
49	1.9	1.3	No tumor	Cardiomegaly
50	1.5	2.3	No tumor	Alcohol abuse, peripheral neuropathy
51	1.7	95.1	Cancer P	Adeno CA
52	12.1	25	Cancer P	Adenocarcinoma of prostate
53	7.2	1.1	Cancer Ly	Lymphoma, marginal type, untreated
54	6	0.5	BPH/T	Hyperplasia of prostate, TURP
55	6	0.7	Unknown	Serum routine analysis
56	22.4	0.5	Hyperplasia	Schizoaffective disease, hyperplasia of buccal mucosa, no malignancy
57	5.9	1.3	No tumor	Emphysema
58	3.3	28.8	Cancer C/P	Mucinous adeno C of colon, metastatic, PC moderately diff., treated

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
59	14.2	56.7	Metastatic P	PC, M1b, increased uptake at the right 2nd rib
60	18.5	45.9	Cancer P	PC, no metastasis
61	269.7	98.5	Cancer P	PC poorly diff., status post-radical prostatectomy
62	5.6	27.8	Cancer P/T	PC moderately diff., no metastasis, radiation therapy
63	4.8	29	Cancer P/T	PC moderately diff., no metastasis, treated
64	9	41.1	Cancer P	PC moderately diff., no metastasis, treated
65	5.4	28.6	Cancer P/T	PC well diff., no metastasis, TURP
66	3.9	2.2	No tumor	Cannabis Sativa abuse, alcohol dependence
67	5.2	1.1	BPH	TURP, serum routine analysis
68	1.6	1.3	No tumor	Degenerative changes, lower cervical spine
69	33.9	1.7	Metaplasia	History of cystitis cystica, metaplasia, chronic hematuria, bacterial infection
70	7.5	2.6	Unknown	Diverticulosis of the colon
71	4	0.7	No tumor	Sigmoid/descending colonic diverticulosis
72	34.6	1.4	Unknown	Benign hypertension, bipolar affective disorder, serum routine analysis
73	4	2.3	No tumor	Diabetes, proliferative diabetic retinopathy
74	21	64.6	Prostate C	PC
75	6.3	33.2	BPH	Glandular hyperplasia, dysplasia, atrophy, no evidence of malignancy
76	47.1	33.8	Cancer P	PC well diff., no evidence for metastasis
77	17	15.2	Cancer P	PC, untreated
78	31.2	15.6	BPH	Prostate hyperplasia, glandular, needle biopsy, untreated
79	28.2	84.6	Cancer P	PC poorly diff.
80	23.3	1.8	Unknown	Serum routine analysis
81	36	1.5	Unknown	Serum routine analysis
82	19.2	1.2	Unknown	Congestive heart failure, serum routine analysis
83	31	31.3	BPH	BPH, untreated
84	9.6	1.2	Pre-leukem	Hypercellular bone marrow, early lymphoproliferative disorder
85	94.5	0.46	Tumor	Chronic hiliar adenopathy
86	2.5	100	Metastatic P	PC T4N2M1b, treated
87	32.1	2.3	Unknown	Tobacco abuse, serum routine analysis
88	43.5	1.5	Unknown	serum routine assay
89	11.7	0.8	Unknown	Alcohol abuse, peptic ulcer disease
90	34.2	0.2	Cancer P	PC, stage B-II, status post-radical retropubic prostatectomy
91	6.6	0.6	No tumor	Mild degenerative joint disease
92	4.2	1.1	No tumor	Status post coronary artery bypass graft
93	10.5	1.4	Unknown	History of hiatal hernia, esophagitis
94	37.2	1.7	Cancer P/T	PC, prostatectomy 11 years ago, serum routine analysis
95	11.1	1.7	No tumor	Diabetes, hypertension
96	7.8	0.3	Unknown	Serum routine analysis
97	62.1	20.7	Metastatic P	PC moderately well diff., M1b, untreated
98	16.8	4.6	No tumor	Schizophrenia, pneumonia, no evidence of pulmonary malignancy
99	9.5	3.4	Unknown	Serum routine analysis
100	8.4	0.5	Unknown	Serum routine analysis
101	108.6	0.4	Unknown	Serum routine analysis
102	8	0.2	No tumor	Diabetes, benign hypertension, alcohol abuse
103	6.3	0.7	No tumor	Myocardial perfusion defect
104	36	44.8	Cancer P	PC moderately well diff., no metastasis, T2b
105	6.5	2.3	Unknown	Serum routine analysis
106	33.2	34	Cancer P	PC well diff., untreated
107	7.5	33.2	BPH	Biopsies, negative for PC, prostatic displasia, glandular hyperplasia
108	11.5	64.6	Unknown	Prostate enlargement
109	29	1.5	Unknown	Serum routine analysis
110	10.3	0.2	Cancer P	PC, status post-radical retropubic prostatectomy
111	47.3	39	Metast. P/T	PC, well diff., M1b, hormonal therapy
112	53.4	60	Cancer P	PC, T1c, untreated
113	17.2	2.5	Unknown	Degenerative changes of the lumbar spine at L5-S1, no tumor found
114	10.1	1.6	No tumor	Osteoarthritis, diffuse idiopathic skeletal hyperostosis
115	27.5	0.6	Unknown	Insterstitial lung disease, multiple sclerosis, diverticulosis
116	86.6	0.8	Metastatic O	Squamous cell CA of the oropharynx, metastatic, surgery, radiotherapy

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
117	42	0.4	Cancer P	PC, TURP performed 5 years ago, serum routine analysis
118	12.6	0.4	Unknown	Serum routine analysis
119	12.3	0.4	No tumor	Aortic valve sclerosis with severe cardiac dysfunction
120	6.5	0.5	Metast. C/T	Colon carcinoma, multiple lung metastasis, chemotherapy
121	48.3	70	Cancer P	PC moderately diff.
122	42	84.6	Unknown	Serum routine analysis
123	10.8	0.2	No tumor	Coronary artery disease, hypertension, pernicious anemia, hepatitis C
124	21	98.3	Cancer P	PC poorly diff., T3a, no metastasis, resected, serum routine analysis
125	41.1	0.8	Unknown	Serum routine analysis, diabetes mellitus, type II; vascular disease
126	20.1	68.4	Cancer P	Adeno CA; treated
127	15	1.6	Unknown	Chronic obstructive lung disease, hypertension, degenerative arthritis
128	13.6	0.9	Unknown	Serum routine analysis
129	34	17.6	Cancer P	PC well diff., resected, hormonal therapy
130	30.6	85.5	Cancer P/H	PC well diff., no metastasis, Hodgkin's disease
131	12	2	Unknown	Alzheimer's disease, hypertension
132	56.4	0.8	Cancer P/T	PC, post TURP, serum routine analysis
133	10.5	1.2	Unknown	Serum routine analysis
134	8.7	0.6	Unknown	Cerebrovascular accident, chronic renal failure, gout
135	50.4	40.6	Cancer P	Adeno CA prostate
136	42	44	Cancer P	PC moderately well diff., T3a, no metastasis
137	23	160	Unknown	Serum routine analysis
138	6.3	0.5	No tumor	No evidence of pulmonary disease, or lung tumor
139	2.4	20	No tumor	Organic heart disease, arthritis, hypertension
140	6	0.9	Cancer L	Lung mass containing necrotic areas consistent with malignancy
141	12.3	166	BPH	Hyperplasia of prostate
142	15	2.3	Unknown	Serum routine analysis
143	51.6	50.3	Unknown	Elevated PSA; Dementia
144	15	0.5	Unknown	Serum routine analysis
145	5.4	100	Cancer P/T	PC, treated, serum routine analysis
146	76.2	195	Cancer P	PC, no metastasis found
147	82.5	50.2	Cancer P	PC, Multiple sclerosis, Parkinson's disease, serum routine analysis
148	20.7	1.3	Unknown	Serum routine analysis
149	22.5	1.3	Cancer E	Esophageal malignancy, untreated
150	12	0.2	Cancer P/T	Prostatic malignancy, treated, serum routine analysis
151	252	1.1	Metast.atic B	PC, radical prostatectomy; Transitional CA bladder, resected; metastatic
152	12	22	Unknown	Alcoholic cirrhosis of the liver
153	40.2	0.8	Metaplasia	Diabetes, recurrent urinary tract infection, metaplasia
154	72	21.6	Metastatic P	Prostate CA; M1b
155	31.5	0.9	Unknown	Psychiatric disorder, COPD
156	87	88	Metast. P/L	Well diff. CA of prostate; M1b; squamous cell cancer of lung.
157	40	0.7	Cancer C	Well diff. adeno CA of colon
158	309	489	Metastic P/L	PC, treated; Small cell CA of lung, treated; M1b
159	37	0.5	Unknown	Alcoholic, hypertension, serum routine analysis
160	33.4	45	Cancer P	Prostatic malignancy, treated, serum routine analysis
161	21.7	1.8	Unknown	Serum routine analysis
162	36	31	Unknown	Serum routine analysis
163	18.1	0.4	Unknown	Loss of disc space at L5-S1
164	36.2	0.7	Unknown	Serum routine analysis
165	13.1	42.3	Metastatic P	PC, M1b; Colon CA, treated; normal screening examination, remission.
166	36	0.4	Unknown	Serum routine analysis
167	3.5	2.2	No tumor	No evidence of cancer
168	32.2	5.2	Cancer P	PC, treated 3 years ago; serum routine analysis
169	7.2	0.6	Metastasis/T	Lymph node with poorly diff. adeno CA, unknown primary, remission
170	6	12.1	Metastatic P	PC poorly diff., M1b, radiation therapy, Sr-89 therapy, bone healing
171	34.2	0.2	Cancer L/P	Neck Lymphoma, poorly diff, status post-chemotherapy, PC treated
172	64.2	6.1	Cancer	Hematology/Oncology, chemotherapy
173	44.4	0.2	Cancer B	Transitional cell bladder CA, stutus post-chemotherapy
174	45.6	46	Cancer P	PC, TURP

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
175	31.6	0.4	Unknown	Serum routine analysis
176	618	2	Unknown	Status post massive cva, heparin, COPD, protate enlargement
177	9.1	2.2	No tumor	COPD, atherosclerosis
178	35	19	Cancer P	Adeno CA
179	69	0.5	Unknown	Degenerative arthritis
180	7	24	No tumor	Prostatic needle biopsy, negative for malignancy
181	26.1	3.2	Unknown	Degenerative arthritis, left lung basilar consolidation, pleural effusion
182	12.6	6.1	No tumor	Presenile dementia
183	13.2	25.2	Cancer P	Adeno CA prostate
184	34.8	1.2	Unknown	High blood pressure
185	582	102	Metastatic P	PC poorly diff., T4a/M1b, status post-treatment
186	370	2	Unknown	COPD, cerebellar infaction of unclear etiology one year ago
187	42	66.5	Cancer P	PC well diff., T1c/M0; orchiectomy; Multiple colonic polyps
188	15	24.7	Cancer P	PC poorly diff., T2, status post TURP
189	30	ND	Cancer C	Well diff. colon adeno CA, resected, L metastasis, stage IV,chemotherapy
190	417	ND	Cancer PA	Well diff. pancreatic adeno CA, resected, chemo/radiation therapy
191	22	ND	Cancer T	Squamous CA of R tonsil/base of tongue, T2N0M0, resected, radiation
192	45	ND	Cancer L	Syndrome of antidiuretic hormone production by lung CA, 2 cm lung mass
193	8.6	27.4	Cancer P	Adenocarcinoma of prostate
194	43.8	44.2	Cancer P	Adenocarcinoma prostate
195	61.2	23.6	Cancer P	Malignant neoplasia of prostate diagnosed 3 years ago
196	2.9	1	No tumor	Coronary artery disease, calcified aorta, COPD, esophageal diverticula
197	12.4	ND	Cancer R	Rectal adeno CA, post-radiation therapy, chemotherapy, Tuberculosis
198	4.4	1.4	BPH	TURP 1 year ago, normal patient
199	2.6	21.1	Cancer P	Adeno CA; M0
200	2.6	0.4	Cancer P	PC well diff., TURP 6 years ago, no evidence of disease
201	4.4	90.7	BPH	BHP diagosed 3 years ago
202	5.4	0.2	Cancer P	PC T3a, prostatectomy, radiation, 2 y ago; CoCA treated 7 y ago
203	14.1	24	Cancer P	PC T3a, prostatectomy, radiation, 3 y ago; serum routine analysis
204	6.8	0.4	No tumor	Repaired hydrocele, no malignancy, diabetic, chronic renal failure
205	40	3356	Metastatic P	PC poorly diff., M1b, treated, strontium therapy for pain, 3rd MPS analysis
206	48	ND	Cancer H	Hepatocellular cancer, untreated
207	36.3	1.2	Cancer Lx	Malignant neoplasia of Larynx treated 6 years ago; possible lung metastasis
208	2.5	37	Cancer P	PC T2, treated, no evidence of metastatic disease
209	269	2	Unknown	COPD, cerebellar infaction of unclear etiology 1 year ago
210	954	102	Metastatic P	PC poorly diff., N3/M1b/M1c, prostatectomy, radiation/hormone therapy
211	166.5	1.1	Lung tumor	COPD, 84 y old, heavy smoker for 40 y; infiltrate RL, mediastinal mass
212	10.4	21.5	BPH	BHP, untreated
213	8.5	0.2	Cancer P	PC well diff.T2c/N0/M0, radical prostatectomy 6 month ago
214	65	0.4	Cancer Ly	Poorly diff. non-Hodgkin's lymphoma, III-B, dignosed 12 y ago
215	3.3	0.3	No tumor	Serum routine analysis
216	2.3	0.2	Cancer P	PC well diff., T1/N0/M0, status post-radical prostatectomy, remission
217	44.9	0.8	Unknown	Hematology-Oncology, serum routine analysis
218	6.5	1.8	Cancer P	PC well diff., T1/N0/M0, status post-prostatectomy, remission
219	2.8	0.9	BHP	BPH untreated
220	3.5	40.8	Cancer P	PC poorly diff., T2a/N0/M0, resected 6 months ago, remission
221	10.3	0.4	No tumor	Rheumatoid arthritis
222	162	154	Metastatic P	PC poorly diff., T3a/N2/M1b,TURP 2 y ago; radiation/strontium therapy
223	28.5	1.1	Unknown	No evidence of bony destruction by X-ray survey
224	7.5	41.3	Cancer P	PC poorly diff., T2a/N0/M0, TURP 6 months ago, remission
225	28	2.5	Unknown	Internal carotid artery stenosis
226	14.1	34	Cancer P	PC well diff., T2c/N0/M0, resected 3 monts ago, radiation therapy
227	39	1	Unknown	Levothyroxine replacement therapy
228	36	34	Metastatic P	Well diff. adeno CA of prostate; T3aN2M1b; metastasis in hip.
229	12.3	0.2	Cancer Pen.	Malignant neoplasia of penis body, resected 4 years ago
230	38.1	14.5	Cancer C	Duke's B colon CA, elevated PSA
231	22	1.2	Cancer P/E	Esophageal CA, BHP, TURP, adenomatous colonic polyps
232	13.2	64	Cancer P	Well diff. adeno CA; T1c

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
233	31.5	3.3	Unknown	BHP diagnosed and treated 6 years ago, serum routine analysis
234	79.2	20.8	Tumor P	Multiple colonic polyps, prostatic nodule, elevated PSA
235	6	0.8	No tumor	No rib fracture is noted
236	6.8	245	Cancer P	Adenocarcinoma prostate
237	8	1.1	No tumor	Left carotid endarterectomy, serum routine analysis
238	19	21.8	BHP	Hyperplasia, squamous metaplasia
239	4.1	0.8	No tumor	Serum routine analysis
240	36.4	16	Cancer L	Adenocarcinoma of lung; Benign prostatic hyperplasia of prostate
241	11.7	0.8	No tumor	Serum routine analysis
242	3.1	12.1	BHP	Hyperplasia, glandular, TURP 9 months ago.
243	9	0.8	No tumor	Left foot infection, gangrene, necrosis, multiple kidney cysts
244	12	13.8	Unknown	Elevated PSA
245	5.8	0.1	No tumor	Emphysema, hypertension
246	6.4	58	Cancer P	Prostate cancer, treated 1 year ago, no evidence of metastasis
247	21	1.1	Unknown	Hypertension, tobacco abuse-continuous, COPD
248	23.2	18.5	Cancer P	PC 3 years ago, remission, M1b, marked improvement, no new lessions
249	9.3	1.1	No tumor	Hypertension
250	34.7	13.3	Unknown	Elevated PSA, lingular lung infiltrate
251	36.2	1	Cancer P	PC well diff., T2c, N0M0, radical prostatectomy,
252	28	24.7	Cancer P	PC well diff., T2b/N0M0, diagnosed 5 months ago, no surgery, follow up
253	37.5	1	Tumor Thy	Large multinodular goiter, with multiple areas of decrease activity
254	17.2	16.3	Cancer L	Squamous cell CA of lung
255	14.8	1.6	Unknown	History of stroke, focal brain hypodensity
256	21.4	51.4	Cancer P	PC no treatment, T2b
257	204.4	10.5	BPH	BPH diagnosed 1 year ago, untreated; tobacco abuse, schizophrenic
258	79	331	Cancer P	PC untreated
259	7.3	ND	No tumor	Alcoholic cirrosis of liver, end stage, 300 pound patient, AFP 15,767
260	9.5	32.9	No tumor	Status post-kidney transplant, hepatitis B, elevated PSA
261	34.6	71	Metastatic P	Osteoblastic metastasis.
262	10.8	3.2	No tumor	Benign hypetension, hepatitis
263	21.1	16	Cancer P	Well diff. adeno CA of protate; T2a
264	26.6	0.4	Unknown	Serum routine analysis
265	17.3	65.3	Metastatic P	PC M1b, treated 5 months ago, remission
266	13.5	2.6	No tumor	Hypertrophy of kidney, Paget's disease, schizophrenia
267	73	28.5	Tumor	Hamartoma, elevated PSA, cancer has not been ruled out
268	32.8	2.9	Unknown	Congestive heart failure, pleural effusions
269	30.3	17.3	Cancer P	PC well diff., treated, T2/M0, Hodgkin's disease, stage I
270	7.4	7	No tumor	Malignant hypertension, emphysema, COPD, heart failure
271	12.3	20.7	Unknown	Elevated PSA
272	160.6	0.4	BPH	TURP 4 years ago, chronic renal failure
273	86.3	32	Tumor L	Meningioma 4 years ago; possible metastasis in 5th rib, lung node
274	47	0.3	Cancer C/P	PC well diff. T3c, radical prostatectomy, Rad., 2 y; Colon cancer 7 y ago
275	34	253	Cancer L/P	Squamous cell CA of lung, well diff., PC well diff., hormone therapy
276	37	ND	Unknown	Hematology/Oncology
277	16.1	1.9	Unknown	Serum routine analysis
278	3	16.2	No tumor	Hypertension, elevated PSA
279	45	6	Cancer P	PC well diff., 6 m ago, T2bM0, treated
280	27	62.7	Cancer P	PC, unverified
281	6	ND	No tumor	Euthyroid, Alcoholic, post-traumatic stress disorder
282	9.7	ND	No tumor	Euthyroid
283	2.3	ND	No tumor	Euthyroid
284	30.6	ND	Cancer C	Adenocarcinoma of sigmoid colon
285	42.2	ND	Breast T	Euthyroid, fibroadenosis of breast, inactive TB
286	36.5	ND	Unknown	Hyperthyroid, diabetes, COPD,
287	4.3	ND	No tumor	Hypothyroid, Grave's disease, treated with I-131
288	3.1	ND	No tumor	Hypothyroid
289	111.3	1	Metastatic-S	Metastatic CA, squamous cell; tongue and tonsil; M1b
290	46	ND	Unknown	Hypothyroid, post-surgical, chronic renal insuff., hypercholesterolemia

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
291	27	ND	Brain C	Meningioma
292	4.1	ND	No tumor	Euthyroid, post-traumatic stress disorder, hypertension
293	14	ND	Unknown	Euthyroid
294	14.5	ND	Unknown	Euthyroid
295	4.1	3.4	BPH	Euthyroid, mild prostatic hyperplasia, treated
296	64.2	0.7	Unknown	Euthyroid
297	133.5	0.4	BPH	TURP 4 y ago, COPD, rib fracture, hematuria
298	85.6	245	Cancer P	PC
299	3.4	ND	No tumor	Hyperthyroid, osteomyelitis, R-foot
300	5.5	ND	No tumor	Euthyroid
301	15.2	ND	Unknown	Elevated AFP 32.2
302	24.8	ND	Unknown	Euthyroid
303	56.7	ND	Cancer C	Sigmoid colon adeno CA; CEA 699
304	8.3	ND	No tumor	Euthyroid, rheumatoid artritis
305	38.1	ND	Cancer C	Colon Adeno CA resected 2 y ago; CEA 111; BPH/TURP 2 y ago
306	19.8	0.7	Unknown	Status post-coronary bypass
307	25.3	ND	Cancer	Euthyroid, alcoholic cirrhosis liver; history of cancer treated 1 y ago
308	10.4	ND	No tumor	Euthyroid
309	6.4	ND	No tumor	Euthyroid
310	248	0.4	Unknown	84 y old with anemia, hematuria
311	6.3	11.6	No tumor	Osteoarthritis
312	4.1	1.9	No tumor	Serum routine analysis
313	7.1	18	Cancer P	CA prostate, T3/M0, treated 6y ago, remission; diverticulosis of colon
314	11.3	2.7	No tumor	Serum routine analysis
315	29.6	13.4	Unknown	History of Pulmonary TB inactive; right upper lobectomy
316	9.3	2.3	No tumor	Serum routine analysis
317	9.9	17.4	BPH/CAK	Kyney cancer, status post L nephrectomy, no evidence of disease
318	26	0.8	Unknown	Osteorthritis
319	7.8	ND	No tumor	Euthyroid, depression
320	7.4	ND	No tumor	Euthyroid, cardiomegaly
321	8.5	0.6	No tumor	Serum routine analysis
322	104	0.4	Unknown	84 y old with chronic renal failure, BPH/TURP 4y ago, heart failure
323	7.8	35.5	Cancer P	PC well diff., T2M0, resected 6 m ago, remission
324	4.3	0.7	No tumor	Degenerative arthritis, hypertension, peptic ulcer
325	186	>1000	Cancer P/Lk	101 y old male, CL leukemia, L femur fracture, PC metastatic/PSA:11281
326	31.2	0.2	Cancer Skin	Well diff. squamous cell carcinoma, removed 2 w ago
327	5	0.7	No tumor	Serum routine analysis
328	42	19.4	Cancer P	PC well diff., T2M0, prostatectomy 6y ago, hormonal treatment
329	3.1	ND	No tumor	Hypothyroid, hypertension, diabetes
330	5.8	18.9	Cancer P	PC well diff., T2M0, prostatectomy 7 m ago
331	30	1.5	Metastasis L	Metastatic lung cancer, primary unknown
332	4.7	26.6	Cancer P	PC well diff., T3aM1b, treated 3 y ago, marked improvement, remission
333	19.5	2.2	Tumor L	Right hiliar mass consistent with cancer
334	9.5	ND	No tumor	CEA: 420; bilateral calcified lung granulomas
335	122.2	0.4	Unknown	84 y old with hypertension, COPD, anemia, rib fracture; BPH/TURP 3 y ago
336	30	534	Cancer P	PC well diff., T3M0, treated 6 m ago
337	3.3	0.3	Cancer P	PC well diff., T3bN0M0, prostatectomy 2 m ago
338	2.3	0.2	Cancer P	PC, T1N0M0, prostatectomy, end stage liver disease, high ferritin
339	50.8	ND	Unknown	Hypothyroid, protein malnutrition (kwashiorkor).
340	12.8	ND	No tumor	Hyperthyroid, schizophrenia, COPD,
341	337.2	45	Cancer L	Sputum (+) for malignant cells; 10×8 cm RL lobe tumor, pleural effussion
342	26	1.9	Unknown	Diabetes
343	52	69	Metastatic P	PC treated 3 y ago; metastatic M1b
344	8	0.2	Cancer P	PC treated 5 y ago, no evidence of disease
345	58.3	685	Metastatic P	PC, T3M1b, radiostrontium treatment, radiation
346	7.7	2.7	No tumor	Hypertension, diabetes, congestive heart failure
347	6.8	21.2	Cancer P	PC well diff., T1cM0, treated
348	36	1.5	BPH	Psycogenic polydipsia, COPD, tobacco abuse

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
349	42.5	69	Cancer P	PC treated 6 y ago, recurrence
350	279	5.7	Unknown	Urosepsis, bladder outlet obstruction
351	36.2	43.4	Cancer P	PC, T3aM0, untreated
352	5.4	0.6	No tumor	Aortic atherosclerosis, atrial fibrilation
353	4.1	21.7	BPH	Prostate hyperplasia, adenofibromyomatous, needle biopsies
354	5	0.5	No tumor	Diabetes
355	35.6	131	Metastatic P	PC poorly diff., T3cN2M1b, hormonal therapy,
356	192.4	0.4	Unknown	Degenerative arthritis
357	44.1	225	Cancer P	PC, large bilateral pleural effusions
358	7.8	0.3	No tumor	Schizophrenic
359	92.6	186	Metastasis P	PC well diff., T3aN2M1b, diagnosed 1 y ago, hormonal therapy
360	32.1	0.4	Cancer Lx	Malignant neo larynx, 5 y ago
361	62.5	5.4	Cancer P	PC well diff., treated
362	3.2	1.7	No tumor	Serum routine analysis
363	52.5	12.4	Cancer P	Adeno CA; treated
364	715	344	Metastatic P	PC, hormonal therapy
365	1073	1.4	Metastatic	Large L mass; Thoracentesis: malignant cells mucin (+); adenocarcinoma
366	0.2	9.1	No tumor	Diverticulosis of colon
367	72	3752	Metastatic P	PC poorly diff., M1b, treated, strontium therapy for pain
368	50.4	1.1	Unknown	Serum routine analysis
369	10.5	52.7	No tumor	Elevated PSA
370	277	0.2	Tumor	Bladder tumor, patient died
371	36.3	64.7	Metastatic P	M1b, treated
372	62.4	1.7	Cancer L	Adeno-CA of Lung, well diff., T2N0, status post lobectomy, 2 y ago
373	68.4	20.3	Cancer Co	Colon CA, T3N0M0, post hemicolectomy, 2 y ago; protatic nodule
374	73.2	0.2	Cancer P	PC treated, 5 y ago
375	194.4	12.6	Metastatic L	Poorly diff. squamous cell CA of lung; brain metastasis, R parietal area
376	34.8	2.5	Unknown	Serum routine analysis
377	36.6	18.2	Cancer P	PC well diff., T4 M0, TURP hormone therapy
378	67.8	1.4	Proliferation	Extensive pleural thickening on right side of lung
379	13.2	18.2	No tumor	
380	73.5	ND	Cancer Rec	Malignant neo rectum, status post-resection, 2 y ago, increased CEA
381	34.5	ND	Multiple My	Multiple My, end-stage renal disease, dialysis
382	15.3	ND	Metastatic L	Non-small cell lung cancer, T3N2M1b, 13 cm mass, radiotherapy 3 m ago
383	4.2	ND	Breast C	M1b, chemotherapy 5m ago, dramatic remission of bone mets
384	5.1	0.6	Cancer P	PC status post resection 5 y ago. No evidence of PC
385	28.2	436	Cancer P	PC T4, resected 3 y ago
386	14.9	1.5	No tumor	Coronary artery disease, alcohol abuse
387	3.8	37.7	No tumor	Elevated PSA
388	12	7	No tumor	Serum routine analysis
389	30.2	840	Cancer P	PC, T2M0, untreated
390	0.7	4.8	BPH	Hyperplasia, adenofibromyomatous; TURP 5 m ago
391	291.5	1.7	Metastatic L	Non-small cell CA of lung, M1b
392	3.3	248	No tumor	Hypertension
393	5.3	2.2	Cancer C	Colon Adeno-CA, T3N1MX, post-colectomy /chemo 4 m ago, remission
394	3.4	10	BPH	Hyperplasia, adenomyomatous
395	9.8	1.6	No tumor	Status post-hip replacement
396	18.1	27.2	Cancer Co	Colon adeno CA, moderately diff.
397	38	0.6	Unknown	Serum routine analysis
398	546.6	1145	Metastatic P	PC T4N2M1b, untreated
399	4.8	2.1	No tumor	Chronic peptic ulcer
400	15.2	927	Metastatic P	PC T4N2M1b, treated 1 m ago
401	7.2	1.2	Cancer P	PC resected 2y ago
402	2.2	23.3	BPH	BPH untreated
403	3.2	0.6	No tumor	Cardiac disease, hypertension
404	16	12	No tumor	Cardiac disease, hypertension
405	3.5	0.6	No tumor	Emphysematous disease
406	2.7	54.7	No tumor	Elevated PSA

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
407	36.3	12.3	Cancer L/P	Non-small cell lung CA 3x5 cm lesion; Bronchial cytology (+); PC treated
408	156.9	0.3	Cancer Ly	Squamous metaplasia of lung; laryngeal CA resected 2y ago; Chronic RI
409	9.5	ND	No tumor	Gallbladder with gallstone disease
410	24	4.1	BPH	Prostatic needle biopsy: hyperplasia, glandular
411	827.3	ND	Cancer L	Lung cancer suspected
412	56.4	0.2	Tumor L	Right suprahiliar nodule; diabetes
413	549	2.5	Cancer P	PC T4a; bilateral obstructive uropathy; Hemodialysis
414	12.1	1.2	BPH	Status post-cerebral bleed; hypertension
415	9	1.2	No tumor	Benign hypertension
416	7	0.2	BPH	Chronic atrial fibrillation; heart failure
417	669.3	ND	Unknown	Neurocardiogenic syndrome; death without autopsy
418	55.4	0.3	Unknown	Bilateral pleural effusions; septic arthritis
419	32	0.6	No tumor	Diabetes; chronic renal insufficiency
420	3.5	ND	No tumor	Idiopathic cardiomyopathy; diabetes mellitus
421	4.8	14.8	No tumor	Pain medication
422	12.8	1	No tumor	Diabetes mellitus
423	6.9	20.1	No tumor	Urinary infection, retention
424	40.4	0.6	Unknown	Peptic ulcer, esophagitis, deep venous thrombosis, diabetes mellitus
425	4.7	15	No tumor	COPD, cardiopulmonary disease, alcohol abuse, hypertension
426	2.7	1.2	No tumor	Multyple cystic liver
427	4.8	22.2	No tumor	Elevated PSA
428	5.3	58.5	Metastatic P	Prostate M1b; treated
429	2.1	1.4	BPH	BPH on Prost. carc.
430	112	30	Unknown	Elevated PSA
431	5.1	16	BPH	BPH
432	6.9	0.8	No tumor	Malignant neoplasia of bladder treated 6 y ago. No evidence of cancer
433	30.6	23	Cancer P	PC treated
434	6.7	ND	Cancer C	Colon cancer treated 3 y ago. Remission
435	4.1	1.4	No tumor	Hearing problem
436	4.7	ND	No tumor	Liver cirrhosis, active hepatitis C
437	8.1	6.3	BPH	Hyperplasia, adenofibromatosis, 6 m ago
438	2.3	4.1	BPH	Prostatitis, Hyperplasia, glandular inflammation, TURP, 1 m ago
439	8	6.3	No tumor	Calcified granuloma R lung, smoker
440	32.6	11.5	Unknown	Tobacco abuse, anemia, L lingular neumonia
441	31.9	6.9	Cancer P	Adeno CA of prostate
442	5	4.9	BPH	Prostatic hyperplasia, chronic inflammation
443	14	7	BPH	BPH, chronic stomach inflammation
444	2.3	12.1	No tumor	Congestive heart failure, glaucoma
445	6.5	6.4	No tumor	Pulmonary tuberculosis, extensive; no tumor; diabetes mellitus; COPD
446	120	4.5	Cancer P	PC treated, radiation therapy 3 y ago
447	9.7	96	Unknown	
448	33.1	98.1	Cancer P/K	Cancer of prostate or kidney; possible metastatic
449	7	14.4	No tumor	Coronary artery disease
450	8	6.8	No tumor	Benign hypertension
451	48.4	10.5	Cancer P	PC T4a; treated 2 y ago,status post radiation therapy and orchiectomy
452	12.5	112	Metastatic P	PC T4a/M1b; Metastasis in sacrum, sclerosis of sacrum metastatis
453	5.7	37	No tumor	COPD
454	5	9	No tumor	Diabetes mellitus, mild renal insufficiency
455	95.3	353	Cancer P	PC treated 4 y ago
456	3.8	9	No tumor	Serum routine analysis
457	5.3	35	No tumor	Hypertension
458	10.3	9	Cancer P	PC well diff., TURP 1 y ago, remission
459	29.1	30.1	Cancer P	PC focal, T1c/M0
460	9.4	6.8	Cancer B	Cancer of Urinary bladder treated 7 y ago; no evidence of cancer
461	508	62	Cancer L	Pleural fluid suspictious for malignant cells, recurrent pleural effussions
462	8.1	10	No tumor	Serum routine analysis
463	32	29	BPH	Prostatitis
464	6.3	31.3	Cancer P	Diff. CA; T3N0M0; radical prostatectomy

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
465	8.2	18.4	Cancer P	PC well diff., T1c/M0; treated 5 m ago
466	25.5	11	Unknown	Diabetes mellitus, congestive heart failure
467	8.8	14	BPH	BPH
468	9.3	3.7	Prostate C	PC focal well diff. treated 5 m ago; stage I Hodgkin's disease, treated
469	8	1	Metastatic P	PC T3a/M1b, postive bone scan in L2-3
470	60.4	6.6	Metastatic C	Metastatic colon cancer to brain, lung and liver
471	33	326	Cancer P	PC well diff., untreated
472	6.2	5.3	No tumor	Serum routine analysis
473	20.1	128	Metastatic P	PC poorly diff., T3a/M1b
474	11.3	5.4	BPH	Hyperplasia, glandular
475	24.1	37.8	Unknown	Persistent lung infiltrates and pleural effusions
476	49.2	7.8	Unknown	COPD, history of erosive esophagitis
477	4.4	ND	No tumor	Cholelitiasis, diffuse parenchymal liver disease
478	10.6	1.4	No tumor	Status post- liver transplant
479	32.8	39	Cancer P	PC well diff., T1c/M0; orchiectomy
480	37.6	6.6	Unknown	Cardiomegaly
481	24.2	7.4	Cancer P	Well diff adeno CA; T2; treated 1-y ago
482	34	15	Pineal tumor	Possible pineal tumor
483	33	279	Prostate C	Adenocarcinoma, T3/M0
484	17	7.5	No tumor	Marked degenerative arthritis
485	12.5	12.1	Prostate C	PC treated 1.5 y ago
486	76	13.5	Prostate C	PC treated 6 y ago
487	280	7.7	Unknown	Congestive heart failure, status post cardiac surgery, CVA, gout, COPD
488	10.7	1	No tumor	Renal vascular disease
489	212	ND	Unknown	Prominent lung infiltrates, smal l granuloma in R lung base
490	9.3	0.6	Cancer P	Status post-resection 5 y ago
491	11.1	10.2	No tumor	Osteoarthritis, generalized
492	40	1.3	Unknown	Serum routine analysis
493	12	10.2	BPH	BPH confirmed by needle biopsy, focal atypia present
494	4.3	9.7	No tumor	Serum routine analysis, elevated PSA
495	7.3	9.4	No tumor	Serum routine analysis, elevated PSA
496	117	25	Metastatic P	Prostate cancer, M1b
497	24	16.4	Prostate C	PC well diff., hyperplasia, T2b
498	54.4	13.2	Basal Cell C	Basal cell carcinoma, margins involved, removed
499	16.1	16.4	Unknown	Coronary artery disease
500	3	10	No tumor	Arthritis
501	10.8	8	BPH	Hyperplasia, dysplasia
502	33.7	36.5	Prostate C	72 y old with history of PC and radiation therapy; T3/M0
503	35.4	1	Unknown	COPD, tobacco and alcohol abuse, no evidence of lung tumor
504	36.1	1.5	Unknown	
505	117	17.2	Metastatic P	Adeno CA; treated
506	33.7	18	Prostate C	Elevated PSA
507	12	158.5	Metastatic P	PC, L4 metastasis, treated
508	19.2	3.2	Unknown	serum routine analysis
509	11.2	29.3	Unknown	Elevated PSA
510	13.8	11.5	Prostate C	PC poorly diff., treated 2 y ago; T2a/M0
511	7.3	1.4	No tumor	No evidence of disease
512	6.2	145	Metastatic P	Patient asymptomatic
513	3.1	15.1	Metastatic P	PC 2 y ago, treated, remission; M1b
514	272	36	Metastatic P	PC post-radiation therapy; stage D2
515	5.5	1	No tumor	Serum routine analysis
516	4.8	27.5	Metastatic P	PC consistent with resolving mets; no new lesions
517	39.3	8.3	Tumor	Benign polyps in sigmoid colon, hyperplasia
518	6.3	17.4	No tumor	Elevated PSA, prostatitis
519	14.6	4.9	No tumor	Coronary artery disease
520	45.5	58	Prostate C	PC, M0
521	5.7	2.2	No tumor	No evidence of malignant disease
522	78	9	Unknown	Elevated PSA, rheumatoid arthritis, 30 pack-year smoking

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
523	37	17.2	Metastatic P	Adeno CA; treated.
524	31	1.3	Unknown	78 y old, anemia of chronic disease, calcified prostate
525	10.4	12.5	No tumor	Benign hypertension
526	3.5	12.5	No tumor	Rheumatic heart disease
527	23.5	1.5	Unknown	Alcoholic cirrhosis, thrombocytopenia
528	5.7	29.6	No tumor	Congestive heart failure, CVA
529	6.6	12	No tumor	Serum routine analysis
530	7.8	1.2	No tumor	Thyroid nodules, heroin-cocaine-alcohol depencence
531	4.5	19.5	No tumor	Chronic prostatitis
532	6	9.5	No tumor	Status post CVA
533	27.2	2.4	No tumor	Large duodenal ulcer, 1.8 cm with active proliferative border
534	5.9	11.4	No tumor	Chronic prostatitis
535	220.3	11.3	BPH	Prostate hyperplasia, adenofibromyomatous
536	11.4	1.8	No tumor	Peptic ulcer disease; diabetes mellitus type II
537	51.2	42.2	Cancer L/P	Poorly diff. squamous CA of lung; untreated; PC treated 9 m ago
538	7.8	17.4	No tumor	Elevated PSA, prostatitis
539	7.6	5	Cancer P/T	PC well-diff. adeno-CA treated 1 y ago; T3M0
540	4.3	12.8	Cancer P/T	PC well-diff. adeno-CA treated 10 months ago, T3M0
541	98.4	12.1	Unknown	69-y-old with urinary track infection, obstructive bowel disease
542	154.3	426	Metastatic P	72-y-old patient with M1b PC
543	18.4	18.3	Lung C/BPH	Adeno CA of Lung resected 6-y ago;recurrence is suspected; BPH
544	3.7	1.3	No tumor	Anxiety disorder; otherwise normal patient
545	12.8	15.1	BPH	Diabetes; brochitis
546	26	25	Unknown	
547	0.2	8.6	Unknown	Serum routine analysis
548	9.6	29.6	No tumor	Congestive heart failure, diverticulosis; COPD
549	30.7	12	Unknown	88-y old; serum routine analyis
550	16.1	47.5	Cancer P	PC well diff.; hormonal therapy; M0
551	11	33.8	BPH	
552	1.3	3.5	No tumor	Cardiac insufficiency
553	12.6	2.4	Unknown	
554	32.7	173	Metastatic P	Well diff. CA; T3aM1b; Treated RT; remission
555	9.8	9	No tumor	Diabetes, gastritis
556	3.8	19.5	Cancer P	Pooly diff. Adeno CA; T2a/M0; treated 2-month ago
557	68	42.2	Cancer L/P	Lung,: poorly diff. squamous cell CA; Prostate: Well diff. Adeno CA
558	40	1216	Metastatic P	Poorly diff. Adeno CA; T3aM1b; TURP; hormonal therapy
559	11.9	15.5	Cancer P	PC Well diff., resected 7-month ago; T2cM0
560	17.8	1.6	No tumor	Duodenal ulcer
561	16.5	41.9	BPH	Serum routine analysis
562	6.1	15.7	Cancer P	Well diff. adeno CA; T1cM0; treated
563	66.7	12.7	Unknown	Serum routine analysis
564	8.9	2.3	No tumor	Arthritis
565	180	15.7	Unknown	Death with autopsy
566	5.3	48.5	BPH	Hypertension
567	151	2	Cancer P	History of prostate cancer
568	4.5	16.9	No tumor	Diabetes; emphysema
569	2.6	15.7	Cancer P	Well diff. adeno CA; T1cM0; treated
570	16.9	3.4	No tumor	Diverticulosis of colon; stomach ulcer
571	14.6	41.7	BPH	Hyperplasia glandular
572	54	12	Cancer P	Well diff. adeno CA; T3; treated
573	13.7	1.7	No tumor	Degenerative joint disease
574	20.6	15.6	No tumor	Sputum: squamous metaplasia; COPD
575	194	13.5	Unknown	Death with autopsy
576	3.8	19.5	Unknown	
577	12.5	143	Unknown	
578	39.5	1216	Metastatic P	Poorly diff. Adeno CA; T3aM1b; TURP; hormonal therapy
579	14.4	1.4	No tumor	Tobacco abuse
580	46	158	Metastatic P	Adeno CA; T4N2M1b; Radiotherapy; Bone scan unchanged for 6-month

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
581	5.5	4	No tumor	Normal subject; DJK
582	37.3	95	Metastatic P	Adeno CA; T4aN2 diagnosed 4-y ago; hormone treatment
583	602.5	2984	Metastatic P	Adeno CA; T4aN2; diagnosed 4-y ago; hormone treatment
584	10.2	0.1	No tumor	Diabetes
585	69.2	37.3	Cancer P	Poorly diff. Adeno CA
586	45.3	146.7	Unknown	Urinary tract infection. Death due to sepsis and renal failure
587	6.8	0.6	No tumor	Diabetes; arteriosclerotic heart disease
588	71.1	22.7	Cancer C	Colon CA; status post-resection 4-y ago. Multiple polyps in colon
589	32.7	15.2	Cancer P	Serum routine analysis
590	42.9	1.8	Unknown	Serum routine analysis
591	4	11.2	No tumor	Elevated PSA
592	51.9	11.9	Unknown	
593	31.2	0.1	Unknown	Arthritis
594	22.4	15.6	Unknown	COPD; diabetes; squamous metaplasia of bronchus
595	56.8	22.4	Cancer P	Patient with history of prostate cancer
596	80.1	2	BPH	BPH diagnosed 3 y ago. COPD
597	11.4	29.4	Cancer P	Well diff. adeno CA; T1cM0
598	241	8.8	Unknown	Respiratory failure; anemia
599	10.1	1.4	No tumor	Serum routine analysis
600	400	10.6	Cancer P	Stage IV sacral decubitus ulcer; elevated PSA
601	8.3	30.7	Metastatic P	PC 4-y ago; M1b; Bone scan: complete resolution of mets; no new lesions
602	8.7	0.2	No tumor	Diverticulosis of colon; hypertension
603	6.3	9	Cancer P	PC treated 8-month ago
604	46.1	ND	Unknown	Elevated CEA
605	7.2	ND	Metastatic C	Colon CA; Metastatic; status post-chemotherapy and surgery
606	4.6	ND	Metastatic C	Colon CA, status post -left colectomy 3-y ago; chemotherapy
607	169.4	ND	Metastatic C	Well diff. adeno CA; status post colectomy and chemotherapy
608	32.5	ND	Tumor	Smoker with choroid tumor
609	155	1.3	Cancer P	History of prostate cancer; hormonal treatment
610	9.8	7.4	No tumor	Cardiomegaly
611	15	145	Metastatic P	M1b PC treated
612	20.4	53.5	Prostate C	Serum routine analysis
613	11.4	18.2	BPH	Hyperplasia, glandular; inflammation
614	34.9	0.2	Unknown	Serum routine analysis
615	35.5	30	Unknown	Elevated PSA
616	26	44.7	Cancer C/P	Duke's C colon CA; T4M1b 5-y ago; resection, chemo and rad. therapy
617	83.4	0.6	Unknown	Serum routine analysis
618	30.5	27.5	Unknown	Elevated PSA, serum routine analysis
619	35	10.3	Cancer Ly	Lymphoma, large cell type 2-y ago; chemo/radiation therapy
620	32.4	0.4	Prostate C	Hystory of prostate cancer; hormonal treatement
621	10	16.1	Cancer P	Prostate CA; treated
622	19.3	11.1	BPH	Prostate: glandular hyperplasia
623	8	2.3	No tumor	Sigmoid colon diverticulosis
624	33.1	17.3	Cancer C	Status post-resection for well-diff. adeno CA of colon
625	316.4	28.6	Unknown	Hip infection of the right total hip arthroplasty; femur fracture; osteomyelitis
626	7.2	1.5	No tumor	Aortic arteriosclerosis
627	6.1	11.2	No tumor	Serum routine analysis
628	45.2	22.7	Tumor C	Colon: Multiple adenomatous polyps; hyperplasia; atypia
629	133.2	ND	Cancer Leuk	Chronic lymphoid leuk; progression; died 48-h after analysis
630	2090	ND	Metastatic B	Transitional Bladder CA, resected; Mets: Lung, liver, bone; deceased
631	5257	ND	Cancer L/Le	Chronic lymphocytic leuk; Lung cancer; treated. Progression
632	331	4.5	Metastatic L	Small cell carcinoma of the lung;liver metastasis
633	4.1	ND	Unknown	Serum routine analysis
634	14.7	ND	No tumor	Chronic gastric inflammation
635	340	ND	Cancer Ly	Hodgkin's lymphoma; recurrent lymphadenopathy, progression
636	7.1	30.7	Metastatic P	M1b; bone scan shows almost complete resolution of metastatic disease
637	14	8.3	Metastatic	84-y old with lymphoma and PC; chemotherapy; remission
638	466	28.6	Unknown	86-y old with elevated PSA

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
639	33.6	ND	Lymphoma	Extensive adenopathy minimally decreased after treatment
640	8.3	4.5	Cancer M	Melanoma; M0; no evidence of disease
641	60.8	ND	Metastatic	47-y old with recurrent medulloblastoma with bony metastasis
642	564	5.9	Metastatic C	Well diff. Adeno CA of colon with liver and bone mets. Prostate: BPH
643	10.1	4.5	Cancer M	Melanoma; M0; no evidence of disease
644	8	5	Cancer P	84-y old with Prostate Adeno CA; radiation therapy
645	4	2.5	No tumor	Hypertension
646	19.2	30.7	Metastatic P	M1b; bone scan shows almost complete resolution of metastatic disease
647	90.3	135	Metastatic P	PC surgery 3-y ago. M0
648	149	ND	Metastatic	47-y old with recurrent medulloblastoma with bony metastasis
649	5	59.7	No tumor	Hypertension; elevated PSA
650	483	15.6	Unknown	88-y old with hypothyroidism; BPH; post-renal obstruction; urosepsis
651	30.8	1.3	No tumor	Gastric ulcer
652	32	85.3	Cancer P/B	PC T3a; TURP 2-y ago; Transitional cell carcinoma of bladder
653	158	40	Metastatic P	PC T3M1a
654	6.2	ND	No tumor	Serum routine analysis
655	16.8	9.1	No tumor	Serum routine analysis
656	11.5	43.3	Cancer P	Well diff. adeno CA; T2M0, treated
657	5.9	1.2	No tumor	Cardiomyopathy
658	6.3	7.2	No tumor	Hypertension; esophageal dismotility
659	4.7	16.5	BPH	Prostate: glandular hyperplasia; chronic inflammation
660	9.7	8.4	BPH	Prostate: nodular hyperplasia
661	67	40.1	Cancer P	History of prostate CA
662	8	1.3	No tumor	Myocardial ischemia
663	44.5	9	Unknown	Renal insufficiency
664	3.9	12.4	No tumor	Arthritis; degenerative joint disease
665	1.7	28	BPH	Prostate: Glandular hyperplasia, atypical
666	36.5	0.9	Unknown	Diabetes
667	65.7	ND	Metastatic C	Adeno CA of Colon, resected 2-y ago; Lung metastasis increasing in size
668	47.4	ND	Metastatic C	Status post-resection of colo-rectal cancer 3-y ago; liver metastasis
669	10.5	0.5	No cancer	Patient with polyclonal gammopathy; no evidence of cancer; diabetes
670	2	18.3	Metastatic P	PC M1b; hormone treatment: Bone scan: no active metastic disease
671	5.1	15.7	Cancer P	Focal squamous adeno CA of prostate; treated 6-month ago
672	40	85.3	Cancer P/B	Prostate: T3a; Bladder: transitional cell CA; resected 2-y ago
673	2.5	12.4	No tumor	Arthritis; degenerative joint disease.
674	76	135	Metastatic P	PC orchiectomy; hormonal therapy; M0
675	69.6	ND	Metastatic C	Adeno CA of Colon, resected 2-y ago; Lung metastasis increasing in size
676	0.7	7.2	No tumor	Hypertension; esophageal dismotility
677	20	ND	Metastatic L	Metastatic to lung and brain.
678	1.5	0.3	No tumor	Status post left frontoparietal infarction
679	4.7	244	Cancer P	TURP 4-y ago; serum routine analysis: elevated PSA
680	19.3	14.1	Cancer P	PC: Poorly diff. adeno CA; T3aM0; treated 3-y ago
681	10.5	1.6	No tumor	Serum routine analysis
682	1.8	12.4	No tumor	History of duodenal ulcer; congestive heart failure
683	5.3	279	Unknown	Multi-infarct dementia; elevated PSA
684	2	17.2	No tumor	Elevated PSA
685	50.1	ND	Metastatic C	Well diff. sigmoid colon adeno CA resected 6-m ago; liver metastasis; chemotherapy
686	1.3	0.7	No tumor	Insulin-dependent diabetes; hypotension
687	2.8	25.4	Metastatic C	Post-colectomy 1 y ago; Dukes C; well diff. colon CA; chemotherapy
688	17.6	15.4	No tumor	Cardiomyopathy
689	432	12.4	BPH	BPH; erythema multiforme; severe drug reaction; COPD; gout
690	2	0.9	No tumor	Serum routine analysis
691	33.4	182	BPH	BPH treated with Proscar. Bladder neck obstruction
692	12	15.4	Tumor	5 cm hiliar mass, no change for 2 years. Possible cancer. No treatment
693	6.6	1.4	No tumor	No evidence of cancer.
694	15.3	11	No tumor	Hypertension
695	6.2	160	Metastatic P	Radical prostatectomy 9-y ago; T3aM1b; Hormone/Rad. treatment
696	5.5	0.4	No tumor	Diabetes

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
697	3	16.4	No tumor	Cardiomyopathy
698	5.2	15.4	No tumor	Prostatitis: chronic inflammation. Negative for malignancy
699	89	48	Cancer M	Urinary infection; Skin of head Malignant melanoma; M0
700	9	48	Metast. C/P	Colon and prostate CA; surgery 2-y ago; chemotherapy
701	14.4	0.6	No tumor	Serum routine analysis
702	16.7	0.5	No tumor	Serum routine analysis
703	11.6	28.8	Cancer P	Poorly diff. prostate CA; T4aM0; TURP 6-m ago; remission
704	4.7	16.2	No tumor	Actinic keratosis
705	63.8	15.4	Metast. P/B	Well diff. adeno CA prostate; Transitional cell CA of bladder
706	8	15.3	Cancer P	Adeno CA prostate 2-y ago; T2cM0; TURP; hormone therapy
707	4.3	ND	No tumor	Normal subject
708	412	ND	Metast. Ade	Adeno CA metastatic to liver; mucin positive; untreated
709	2.4	ND	Metastatic C	Dukes C; colectomy 7-y; hepatic lobectomy; 3-y; chemo.; remission
710	6.9	0.6	No tumor	Diabetic; foot infection
711	5	ND	Cancer C	Duke's stage III, 1-y ago; chemotherapy; remission
712	10.8	ND	Cancer C	Duke's C colon CA; chemotherapy; remission
713	14	2	Metastatic E	Esophageal CA 3-y ago; M1b; Recurrent esophageal CA
714	44.1	ND	Cancer C	History of colon cancer. Elevated CEA
715	313.6	1999	Metast. P/L	Small cell CA of Lung; M1b; prostate CA; Ra-chem-therapy; recurrence
716	3.8	21.5	No tumor	No evidence of cancer
717	3.4	4.1	No tumor	Insulin-dependent diabetes
718	9.4	10.2	No tumor	Insulin-dependent diabetes; hypertension. Diverticulosis of colon
719	39	11	Cancer P/L	Prostate CA treated 1-y ago; Lung: Non-small cell CA, unresectable
720	9.2	4.3	No tumor	Low back pain; no evidence of cancer
721	1.3	30.5	No tumor	History of COPD
722	30.1	32.3	Cancer P	Adeno CA of prostate; T1cM0; untreated
723	31.5	2.7	Unknown	History of COPD
724	47.6	13.6	Cancer T	Tongue carcinoma; resected 6-m ago; BPH, untreated. Pharyngeal mass
725	2.7	14.7	No tumor	No evidence of cancer
726	14.6	0.3	Unknown	Serum routine analysis
727	499.4	1326	Metast. P/L	Small cell CA of lung; M1b; Prostate CA; Ra-chem-therapy; recurrence
728	6.9	229	Metastatic P	Well diff. CA; T3aM1b; Treated RT; Deceased
729	2.3	4.1	No tumor	No evidence of cancer
730	78.3	381	Metastatic P	Adeno CA prostate, M1b
731	2.8	1	No tumor	Hypertension
732	16	0.2	Cancer P/Le	Prostate CA and leukemia
733	33.3	39.7	Metastatic P	Adeno CA prostate, M1b; active metastasis
734	3.3	70.1	No tumor	Chronic prostatitis; squamous metaplasia
735	32.1	1.5	Cancer P/L	Adeno CA; prostatectomy 3 y ago; lung adeno CA
736	3.3	11.3	No tumor	Hypertension; tobbaco abuse
737	43.2	0.6	BPH/tumor	Mass, right side of trachea; chronic inflammation
738	116	746	Metastatic P	Adeno CA of prostate, M1b; chemotherapy
739	134	0.4	Cancer P	Adeno CA mod. diff; T2cN0M0; prostatectomy 3 m ago
740	26	0.2	Cancer P	PC treated; colon polyps; suspected colon cancer
741	7.2	1.1	No tumor	Benign hypertension
742	8.4	7.4	No tumor	Chronic obstructive pulmonary disease
743	44	8.5	Cancer P	Adeno CA of prostate, treated
744	62	6.8	Cancer P	Well diff. adeno CA; T1c; untreated
745	11	9.6	BPH	Glandular and stromal hyperplasia of prostate
746	10.5	15	No tumor	Elevated PSA
747	5.7	6.1	No tumor	Colon diverticulosis
748	4.2	5.1	BPH	COPD
749	13	0.3	No tumor	COPD
750	74	1.4	Cancer-P/M	Prostatectomy 7 m ago; meningioma, RT, recurrence
751	59	0.4	Unknown	BPH, treated; suspected neoplasia
752	297	0.9	Tumor	Tracheal mass, squamous epithelium; no CA
753	18.6	9.2	BPH	TURP 2 y ago
754	3	7.6	Cancer P-R	Adeno CA of prostate; hormonal therapy; remission

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
755	2.1	ND	Cancer B-R	Breast cancer; remission
756	4.8	0.2	Cancer P-R	Diff. CA; T3aN0M0; radical prostatectomy 2 y ago
757	26	0.7	Unknown	Tobacco abuse
758	3.3	7.6	No tumor	Myocardial ischemia
759	423	276	Metastatic-P	Mod. diff. adeno-CA; M1b
760	4	10	Cancer-P-R	Adeno-CA; surgery 3 y ago; remission
761	30.3	0.5	Unknown	Serum routine analysis
762	3.3	11.4	BPH	Glandular hyperplasia of prostate
763	54	1.5	Unknown	Possibly Paget's disease; or metastasis
764	31	12	Cancer-P	Adeno CA 3 y ago; M0
765	36	55	Metastatic-P	Adeno CA 4 y ago; M1b
766	22	9	Unknown	Elevated PSA; cardiomyopathy
767	126	71	Metastatic-P	Poorly diff. adeno-CA; M1b
768	10.8	0.3	Cancer B	Inflammation of pyloric mucosa; basl cell CA
769	32	8.6	Cancer-P/M	Well diff. adeno-CA; meningioma, surgery/radiation
770	5.7	0.5	BPH	TURP, 1y ago
771	3.6	16.4	Unknown	Elevated PSA, serum routine analysis
772	4.5	9	No tumor	Congestive heart failure; skull fracture, craneotomy
773	3.6	60	No tumor	Spinal cord injury; paraplegic
774	23	0.5	Unknown	Serum routine analysis
775	17	8.2	Cancer -P	Adeno CA; M0
776	582	2750	Metastatic-P	Adeno CA; M1b; bone marrow BX: poorly diff. CA
777	91.8	1	Unknown	
778	112	13	Unknown	Elevated PSA; bifronto parietal brain infarcts
779	63.3	11	Cancer-P	TURP
780	10.2	0.5	Cancer-R	Rectal CA; treated 3 y ago
781	14.1	9.2	Unknown	Elevated PSA
782	55.5	0.5	Unknown	Serum routine analysis
783	153	2.2	Unknown	Arthritis
784	3	0.7	No tumor	Osteoarthritis
785	2.1	18.4	Cancer-P-R	Well diff. CA; T3NXM0; status post rad. therapy; remission
786	31	32.5	Cancer-P	Mod. well diff. CA; T1c; untreated
787	22	0.8	Unknown	Depression
788	197	9.2	Cancer-P	History of prostate CA
789	12.6	0.6	No tumor	Cardiomyopathy
790	33.3	11	Unknown	Degenerative arthritis; elevated PSA
791	29.4	0.2	Cancer-P	Radical retropubic protatectomy 2 y ago
792	11.1	59.1	Metastatic-P	M1b; improvement shown by bone imaging
793	13	38.5	BPH	Chronic inflammation; adenofibromyomatous
794	4.2	0.9	No tumor	Serum routine analysis
795	148	686	Metastatic-P	Adeno CA; M1b, active metastasis
796	19.8	0.5	Unknown	Osteoarthritis
797	78.3	1	Unknown	Patient on Warfarin anticoagulant
798	40.2	117	Cancer-P	Adeno CA prostate 7 y ago
799	84.3	0.7	Unknown	Serum routine analysis
800	10.2	10	Unknown	Elevated PSA
801	2.2	0.2	Cancer-P-R	Retropubic prostatectomy 2 y ago; remission
802	17.1	6.2	Cancer -P	History of prostate cancer
803	32.1	0.6	BPH	BPH treated
804	121	0.3	Unknown	Paraplegia
805	50	0.7	Unknown	Lt. carotid artery stenosis; history of pleural effussion
806	40	17.1	Cancer P	Adeno CA prostate
807	49	52.2	Metastatic-P	Prostatectomy 3 y ago; T3aN2M1b
808	7.8	5.7	Cancer-B-R	Status post-bladder carcinoma treated
809	2.4	12.4	BPH	TURP for BPH 3 y ago
810	18.3	12.6	BPH	BPH, glandular; untreated
811	9.3	2.5	No tumor	Diabetes; cervical spondilosis
812	128	0.7	Unknown	Parplegic; bilateral hydronephrosis

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
813	3.9	15.6	Cancer L-R	Laryngeal CA, laryngectomy 1 1/2 y ago; remission
814	1.8	0.5	No tumor	Shoulder pain
815	15.8	0.3	Unknown	HIV positive
816	9.3	21	Unknown	Serum routine analysis
817	286	2.2	Unknown	Blood transfusion; anemia
818	10	0.4	No tumor	Non-erosive gastritis; esophagitis; diabetes mellitus
819	9	92	Metastatic-P	PC treated
820	225	2.8	Unknown	Degenerative joint disease
821	1.8	13.6	No tumor	Myocardial infarction
822	168.2	ND	Metastatic-C	Adeno CA colon; mets to liver; T3N1M1; progression
823	311	ND	Metastatic-C	Pericardial/pleural fluid: malignant cells; lung mets
824	549	ND	Metastatic-C	Metastasis to omentum, mucinous adeno-CA
825	4.8	10.4	Unknown	Serum routine analysis
826	10.8	0.7	No tumor	Myocardial infarction
827	71.7	66	Metastatic-P	Adeno CA, T3aNXM1b, Sr89 therapy 5 m ago
828	11	17.4	Metastatic-P	Adeno CA, M1b; hormonal therapy, remission.
829	67	2	Unknown	Large hiatus hernia
830	4.8	26.4	No tumor	Hypertension, degenerative joint disease.
831	50.7	1.2	Cancer-R	R Renal CA, nephrectomy 3y ago; end stage ren. dis.
832	4.2	3.1	Cancer-LxR	CA in situ larynx 2y ago, radiotherapy, remission
833	5.4	2.3	No tumor	Serum routine analysis
834	18.6	29	Cancer-P	Adeno CA, treated 5y ago; T1c; elevated PSA
835	2.7	0.8	No tumor	History of urinary infecctions
836	30.6	25	Cancer-Lx	CA of Larynx; surgery 8 m ago
837	10.2	0.8	No tumor	Dementia; alcoholism
838	6.6	11	No tumor	Hematology: anticoagulant therapy
839	83.1	0.6	Unknown	Serum routine analysis
840	56	19	Unknown	Elevated PSA
841	35.2	139.2	Cancer-P	PC diagnosed 6 m ago
842	4.2	0.5	No tumor	Degenerative disease of shoulder joint
843	11.7	0.5	No tumor	History of ureteral stricture.
844	53.1	274	Metastatic-P	PC; Lung cancer: oat cell; treated. M1bN2
845	13.2	14.2	BPH	BPH untreated
846	1.5	1	No tumor	No evidence of malignancy
847	8.4	17.8	Unknown	Traumatic ankle swelling; elevated PSA
848	7.5	1	BPH	TURP 6 month ago
849	5.1	1.5	No tumor	Patient on anti-coagulant
850	46	713	Metastatic-P	Adeno-CA; M1b; hormone treatment
851	10.5	317	Unknown	Serum routine analysis
852	96.3	16.3	Unknown	5 cm mass in mediastinum. Cancer (?)
853	7.8	1	No tumor	History of chronic bronchitis
854	46.5	0.4	Unknown	BPH, TURP 2 y ago
855	5.4	0.8	BPH	BPH, TURP 3 y ago
856	1.5	17.2	No tumor	Benign hypertension
857	33.1	4.5	Unknown	COPD
858	14.7	9.5	BPH	Prostate: atypia by needle biopsy
859	55.5	2.8	Cancer-P	Adeno-CA prostate; TURP 1 y ago
860	83.4	41.5	Metastatic-P	PC, T1c, suspected M1b; patient refused evaluation
861	99.9	50.6	Metastatic-P	Adeno CA 3 y ago; orchiectomy, N2
862	12.6	1	No tumor	COPD, hypercholesterolemia; chronic sinusitis
863	9.2	1.1	No tumor	Serum routine analysis
864	525	11	Unknown	Dehydratation; urinary infection; IV fluids
865	122	21.2	Metastatic-P	PC 6 y ago; extensive osteoblastic Mets; M1b
866	93.3	50.6	Metastatic-P	Prostatectomy 3 y ago; T3aN2M1b
867	18	0.2	Unknown	Osteoarthritis
868	2.1	35	Unknown	
869	8.4	0.8	No tumor	Diabetes, benign hypertension
870	2.8	9	Unknown	Elevated PSA

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
871	13	1.2	No tumor	Chronic smoker
872	20	18.4	Unknown	
873	2.8	1	No tumor	Chronic obstructive pulmonary disease
874	4	35.4	Unknown	Elevated PSA
875	20.2	0.5	Cancer-P	Well diff. adeno-CA; T1cM0; radical prost. 1.5 y ago
876	3.1	14.7	Cancer-P-R	Well diff. adeno-CA; T1cM0; prostatectomy 6 m ago
877	3.5	0.3	Unknown	
878	2.3	386	Cancer-P-R	Poorly diff. Adeno-CA;T2M0; TURP 28 d ago; remission
879	7.8	0.5	No tumor	Hepatitis B
880	19	1642	Metastatic-P	Adeno CA; M1b
881	34.2	1.4	Cancer Lk	Acute monocytic leukemia in partial remission
882	19.4	366	Metastatic-P	Adeno CA; M1b; treated, active mets.
883	33.4	1.9	Unknown	Gangrene of foot; diabetes
884	19.5	1644	Unknown	
885	22	0.6	Unknown	
886	15.2	67	Metastatic-P	Adeno CA 3 y ago; M1b
887	90	2	Unknown	Diabetes mellitus
888	6.6	0.3	No tumor	Tobacco abuse
889	36.1	12.1	Cancer P	Poorly diff. A-CA; TURP 1 m ago
890	32	0.6	Unknown	Osteoarthritis
891	36.7	5.4	Unknown	Two small ulcers of lower esophagus
892	30.6	0.8	Unknown	Bipolar affective disorder
893	52	7.5	Unknown	
894	8.4	0.6	No tumor	Coronary artheriosclerosis
895	108	20.7	Cancer-K	Kydney cancer, nephrectomy 2 y ago
896	10.5	0.4	No tumor	Migrane; amphetamine abuse
897	22	23	Cancer P	PC, adenocarcinoma, T3a
898	65.3	0.5	Cancer-B	Papillary transitional cell CA, treated 2 y ago
899	27.2	18	Cancer P	Elevated PSA
900	160	0.4	Unknown	Prostatectomy; malaria; multiple knee surgery
901	11.7	13.1	Cancer P	Prostatectomy; T2c; Radiotherapy; orchiectomy
902	28.8	19	Cancer P	PC
903	6.3	0.2	No tumor	Benign hypertension
904	15.7	13.7	Cancer-P	Well diff. adeno; T2c; N0M0; prostatectomy; 2y ago
905	32.3	22.8	Cancer-P/C	CA protate; CA colon; Metastatic, treated
906	7	0.2	Cancer-P	T2; N0M0; Radical prostatectomy, 3 y ago
907	5.7	8	Unknown	Serum routine analysis
908	11.4	1.3	Cancer-C	Colon CA;Stage D; liver mets; right colectomy 1 y ago
909	6.8	0.2	Cancer-P	Radical prostatectomy 3 y ago
910	12	0.3	No tumor	Adenomatous polyps, removed
911	30	7	No tumor	Large rectus hematoma; inflammation
912	5.6	0.5	Unknown	
913	25.4	10	Cancer-R/P	Rectal CA, 5 y ago; colostomy; Prostate CA
914	4	0.3	No tumor	Chemical dependence; heroin,alcohol, hepatitis C
915	6.1	0.2	Cancer-P-R	Prostate CA, T2cN0M0; remission
916	5.4	50	Cancer-P	PC 4-y ago; elevated PSA; treated
917	3.2	0.4	No tumor	Sinusitis; nasal polyps; heart disease
918	4.7	9.1	Metastatic-P	Poorly diff., 1-y ago; N3M4b, extensive mets, treated
919	18.7	0.2	No tumor	Coronary artery disease; hypothyroidism
920	7.6	4.7	No tumor	Sinusitis, hypertension
921	59	3.5	Unknown	
922	4.8	9.5	No tumor	Serum routine analysis; cataracts
923	31.2	0.2	No tumor	Chronic renal failure; anemia
924	7.3	8.5	No tumor	Congestive heart disease
925	10.4	0.7	No tumor	Patient under Dilantin therapy
926	7.6	14	Cancer-P	Well diff. CA, T1cN0M0; hyperplasia of prostate
927	10	0.3	No tumor	Cirrhosis of the liver
928	2.9	11	Unknown	Elevated PSA

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
929	96	0.2	Unknown	
930	4	149	Metastatic-P	Mxb stable in No., size; No evidence for progression
931	452	0.2	Unknown	Pneumonia; psoriatic arthritis; renal failure, anemia
932	11	4.2	No tumor	Serum routine analysis
933	3.1	0.6	No tumor	History of kidney stones
934	2.9	4.5	No tumor	Serum routine analysis
935	5.6	0.2	Cancer-P/R	Well diff. adeno; R-prostatectomy, 2-y ago; remission
936	2.4	6.6	No tumor	Serum routine analysis
937	10.1	3.7	No tumor	Hypertension, renal insufficiency
938	3.9	5.1	No tumor	Lumbar spondilosis
939	2.4	0.2	Cancer-P/R	T2bN0M0; radical prostatectomy 1-y ago. Remission
940	9.1	5.7	Cancer-P/R	PC 2-y ago; treated; remission
941	4.4	0.3	No tumor	Serum routine analysis
942	4.5	1	No tumor	Coronary artery bypass graft.
943	19.6	2.3	Unknown	Hypercholesterolemia
944	11.6	0.9	No tumor	Alcohol abuse
945	39	5.3	Unknown	COPD, elevated PSA
946	6.9	1.9	No tumor	Serum routine analysis
947	4.5	0.6	No tumor	Angina; erosive esophagitis; small duodenal ulcer
948	3.4	0.8	No tumor	Cardiomiophathy
949	7.1	7.2	BPH	Hyperplasia glandular; metaplasia, squamous; untreated
950	3.4	1.1	No tumor	Osteoarthritis
951	27.6	2.4	BPH	BPH, Iron deficiency anemia; diabetes mellitus
952	3.4	0.8	No tumor	Psychosis; cocaine dependence; alcohol abuse
953	2.8	11.4	Unknown	Presumed BPH
954	2.7	3	No tumor	Serum routine analysis
955	22.2	1.9	Uknown	Hypercholesterolemia; Lovostatin
956	5.5	1.6	BPH	BPH treated 5-y ago
957	3.9	7.2	Cancer-P/R	PC treated 3-month ago
958	2.1	2.5	Cancer-P/R	Mod. diff. adeno; T1cN0M0; prostatectomy 5-m ago
959	5	2.6	No tumor	Myocardial infarct; esophageal ulcer
960	5.4	2.2	No tumor	Serum routine analysis
961	4.3	0.7	No tumor	Drug, marijuana; and alcohol abuse
962	2.8	1.2	No tumor	Arthritis of the hips.
963	5.9	2	No tumor	Brain shows a right frontal AV malformation
964	3.7	1.3	No tumor	Inguinal hernia
965	3.9	3.2	No tumor	Serum routine analysis
966	23.3	3.2	Cancer-P	Adeno CA; N0M0
967	3.8	0.7	No tumor	Serum routine analysis
968	3.3	2.2	No tumor	Serum routine analysis
969	4.9	1.2	No tumor	Diverticulosis; COPD; peptic ulcer
970	5.9	1	No tumor	Degenerative arthritis
971	5.7	554	Unknown	
972	4.8	10	No tumor	Congestive heart failure, deceased
973	124	6.2	Unknown	
974	6.5	7.8	Unknown	Elevated PSA
975	74	62	BPH	BPH; renal failure
976	5	2.5	No tumor	Benign hypertension; emphysema
977	5.7	7.2	Metastatic-P	Adeno CA; N1M1b; treated 5-months ago; remission
978	32.3	367	Metastatic-P	M1b; treated
979	5.2	6.6	BPH	BPH treated
980	8.2	52	Unknown	
981	37.6	4.1	Unknown	History of erosive gastritis
982	10.8	2.3	No tumor	serum routine analysis.
983	17	8.7	Cancer-P	Well diff. adeno CA; untreated
984	7.8	91	Cancer-P	Poorly diff. adeno; chemotherapy, orchiectomy
985	2.9	17.3	Cancer-P	Moderately diff. adeno; treated 6-month ago
986	5.3	3.6	No tumor	Degenerative arthritis

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
987	4.2	23	BPH	Hyperplasia, glandular; untreated
988	58	4.5	Unknown	Right hiliary mass
989	18	142	Metastatic-P	PC 3 y ago; M1b; flutamide may increase PSA
990	16.1	5.9	BPH	TURP 3-y ago
991	6.5	15.3	Cancer-C/P	Adeno CA colon; protate; treated 5-m ago
992	3.7	38	Unknown	
993	3.3	50	Metastatic-P	Progression of metastatic cancer
994	4.5	1.3	No tumor	Lumbar stenosis, anemia
995	9.5	0.4	No tumor	Serum routine analysis
996	5.5	582	Unknown	
997	30.6	18.2	Unknown	Urinary track infection; degenerative arthritis
998	7.2	0.4	Cancer-P/R	Adeno CA 4-m ago; prostatectomy
999	492	14.2	Unknown	Heart failure; urinary track infection, peptic ulcer
1000	3.8	8.5	Unknown	Elevated PSA
1001	11.3	9	Unknown	Elevated PSA
1002	9	6.4	Cancer-P	Resected 3-y ago; remission
1003	6.2	4.8	No tumor	COPD, peptic ulcer, vascular disease
1004	3.4	52	Metastatic-P	Active metastasis; paliative therapy
1005	3.8	8.3	Cancer-P/R	Pooly diff. adeno, 4-m ago; N0M0; treated
1006	246	12.4	Metastatic-P	Adeno CA; M1b; treated
1007	7.3	1	No tumor	Paraplegia
1008	2.6	5.1	No tumor	Pleuresy; anemia; hypertension
1009	10	5	No tumor	Heavy smoker
1010	3.4	26	Cancer-P	CA prostate 3-y ago; patient refused treatment
1011	4.1	8.8	BPH	Hyperplasia glandular
1012	3.3	172	Metastatic-P	T3a; M1b; strontium therapy
1013	12	1.3	No tumor	Coronary artheriosclerosis
1014	3.1	148	Unknown	
1015	11.8	5.4	No tumor	Benign hypertension, multiple cerebrovascular accidents
1016	3.6	1.2	No tumor	Serum routine analysis; deviated nasal septum
1017	6	14.7	BPH	Chronic prostatic inflammation; no evidence of CA
1018	23	6.4	Unknown	
1019	118	16.9	Metastatic-C	Sig. Colon adeno; BPH; deceased 2-w after RIA
1020	36.8	1.9	Unknown	Pure hypercholesterolemia
1021	51.6	2.3	Unknown	Pure hypercholesterolemia
1022	58	5.3	Unknown	Pulmonary nodule, 0.75 cm in diamter
1023	122	5.7	Unknown	Warfarin anticoagulant; Heart failure
1024	60	9.4	BPH/Can-B	BPH, focal atypia; TC CA bladder 2-y ago
1025	26	5	Cancer-B	Papillary TC CA bladder grade I-II 3-cm; 8-m ago
1026	6.7	4.2	No tumor	Prostatic atrophy; positive PPD
1027	14.8	0.2	Cancer-P	PC 3-y ago; lung infiltrate
1028	319	5.5	Cancer-L	1-cm nodule base R-lung; pleural effusion
1029	19.4	36.2	Cancer-P	Mod. well diff. CA, T1c; 8-m ago; M0
1030	136	6.2	Unknown	
1031	17.6	25	Unknown	Biopsy prostate: atrophy and focal atypia, 7-m ago
1032	11	4.5	Cancer-P/R	PC treated 9-m ago; M0
1033	6.3	5.8	No tumor	Pernicious anemia; Alzheimer's dementia
1034	113	75	Metastatic-P	Prostate CA; M1b
1035	23	7	Cancer-P	PC treated
1036	15	24	Cancer-P	PC treated
1037	14	4.1	No tumor	COPD; coronary bypass
1038	12	9.6	Cancer-P/R	Adeno CA, 1 y-ago; T2cN0M0; raditherapy, remission
1039	27.5	90	Metastatic-P	Adeno CA, 4-y ago; M1b; treated.
1040	3.8	0.2	Cancer-P	Adeno CA 1-y ago; M0; treated; remission
1041	27	1337	Metastatic-P	Adeno T4aN1M1; treated
1042	3.8	1.4	No tumor	Serum routine analysis
1043	56	112	Metastatic-P	Adeno CA 4-y ago; T3aN1M1b; treated
1044	4.8	11	Cancer-P	Poorly diff. atypical; untreated

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
1045	4.7	3.6	BPH	Glandular hyperplasia; biopsy 8-m ago; treated
1046	12	5.4	BPH	Glandular hyperplasia, untreated
1047	30.2	7.6	BPH	Glandular hyperplasia and focal atypia, untreated
1048	8.5	7.2	BPH	Adenomatous hyperplasia
1049	12.5	0.2	No tumor	Cardiac disease
1050	13.6	4.7	No tumor	Diabetes; cardiomyopathy
1051	9	54	BPH	BPH, untreated
1052	9.2	12.6	Cancer-P	Hyperplasia; adeno-CA; treated 2-m ago; T1c.
1053	2.3	9.5	Cancer-P	Prostate cancer; TURP, 1-m ago
1054	38	30.3	Cancer-P	PC; T1c N0M0; TURP, 6-m; BPH; TCCA bladder, 3-y
1055	16	23.4	Metastatic-P	PC, M1b; treated
1056	47	10	Unknown	
1057	7	4.6	Metastatic	Multiple osteoblastic Mets. Unknown primary
1058	75	30	Metastatic-P	Adeno CA; M1b
1059	139	17	Metastatic-P	Adeno CA, 3-y ago
1060	48	10.4	Unknown	4-y ago, junctional nevus with displastic change
1061	5	11	Unknown	
1062	2.6	8	BPH	Unverified
1063	2	13	BPH	Hyperplasia and chronic inflammation
1064	6.1	187	Metastatic-P	Post-chemo.; Osteoblastic; unchanged for 2-m
1065	2	13	No tumor	Emphysema; degenerative joint disease
1066	22	15	Cancer-P	Adeno CA; untreated
1067	87	1594	Metastatic-P	Adeno CA; M1a,b,c.; treated
1068	3	8	Unknown	
1069	2	13	Cancer-P	Adeno CA, 2-y ago TURP, ochiectomy
1070	4	9	BPH	
1071	3.1	8	No tumor	Diabetes
1072	75	18	Cancer-P	Well diff. adeno CA; T2c; M0
1073	3.6	8	Unknown	Serum routine analysis
1074	33.3	30.3	Cancer-P/B	Adeno CA; TURP 6-m ago; TCCA bladder
1075	34	18	Cancer-P	Well diff. adeno; M0, untreated
1076	146	17	Metastatic-P	Adeno CA, 2-y ago
1077	8	9	Cancer-P	69-y old with prostate CA for 13-y
1078	528	20.8	Metastatic-P	Adeno; T3M1b; active mets sacrum; treated
1079	19	7.6	Cancer-P	Well diff. adeno; M0; prostatectomy 1-m ago
1080	2.5	16	Cancer-P	Adeno C; treated
1081	5.6	9	BPH	
1082	13.7	16	BPH	Glandular hyperplasia, chronic inflammation
1083	4	8	BPH	Glandular hyperplasia, chronic inflammation
1084	326	28	Unknown	
1085	4	7	No tumor	Serum routine analysis
1086	196	18.6	Metastatic-P	Adeno; T3M1b; active metis sacrum; treated
1087	1.7	9.2	Cancer-P	Well diff. adeno;T2M0; prostatectomy 3-m ago
1088	5	18	Unknown	Elevated PSA
1089	4.3	7.1	Unknwon	Elevated PSA
1090	19.6	52.4	Cancer-P	Adeno CA; In cancer registry
1091	3	10	Unknown	Benign hypertension
1092	1.5	15	Cancer-P	Adeno CA prostate
1093	2.5	2.3	No tumor	Serum routine analysis
1094	316	538	Metastatic-P	M1b
1095	10.5	91	BPH	Glandular hyperplasia and chronic inflammation
1096	89.4	12.2	Metastatic-L	Prostate CA, treated, multiple lung metastasis
1097	5.2	17	Cancer-P	Adeno CA, T2M0, treated 4-m ago.
1098	4.1	1.8	No tumor	Bipolar affective disorder; drug dependence
1099	6.6	16.9	No tumor	Elevated PSA, arthritis
1100	5.6	11.5	Metastatic-P	Poorly diff. adeno; M1b, osteoblatic, treated, remission
1101	6.2	0.2	Cancer-P	Adeno CA, remission
1102	6.6	48.4	Cancer-P	Well diff. adeno; M0, treated 1-m ago

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
1103	26.7	7.1	Unknown	Elevated PSA
1104	8.8	0.2	Cancer-P	Well diff. adeno; T2M0, radical prostatectomy, 3-m
1105	11	5.7	Cancer-P/Lx	Well diff.;T2M0, prostatec. 6-m; Laryngeal CA, 3-y
1106	25	5.3	Cancer-P	Protatectomy 5-y ago
1107	8	4.6	Cancer-P	Prostatectomy 3-y ago
1108	22.3	5.1	Cancer-P	Prostate CA, 2-y ago
1109	5	8.5	No tumor	Cardiomegaly; elevated PSA
1110	4.6	1	No tumor	COPD, chronic smoker
1111	4.6	8.2	No tumor	COPD
1112	6.4	7.4	No tumor	Degenerative joint disease, L shoulder
1113	8.4	7.8	No tumor	Degenerative arthritis, basal cell CA skin, 5-y ago
1114	11.6	70.2	Unknown	Right ankle injury, elevated PSA
1115	141	0.4	Unknown	Compression of L3
1116	9	24.5	Unknown	Elevated PSA
1117	12.6	20.4	Unknown	
1118	11.3	4	No tumor	Paraplegia, urinary infection
1119	35.5	16.2	Unknown	Biopsy of prostate; atrophy and chronic inflamation
1120	9.1	0.5	Cancer-Ly	History of lymphoma, remission
1121	38	ND	Metastatic-C	Colon CA, 2-y ago; Mets in liver, active
1122	6.5		Metastatic-C	Colonn CA, post-chemo; Liver mets, decrease in size
1123	21.5	3.3	Cancer-C	History of colon CA and polyps
1124	63.2	ND	Cancer-C	Colon CA; pleural effusion, post-chemo.
1125	9	ND	Metastatic-C	Colon CA, liver mets; post-chemotherapy
1126	64	ND	Cancer-C	Colon CA, liver mets; post-chemotherapy
1127	70.4	1	Unknown	
1128	9	215	Metastatic-P	PC with liver mets; treated
1129	26	124	Cancer-P	Well diff. adeno; T2c
1130	19.2	337	Metastatic-P	Well diff. adeno; T3a, M1b,c.; treated
1131	29.6	0.3	Unknown	
1132	48.6	12	Unknown	Elevated PSA
1133	11.6	25	No tumor	Chronic prostatitis, negative for malignancy
1134	8.7	15.7	No tumor	Chronic prostatitis, focal squamous metaplasia
1135	13.7	1.2	No tumor	Serum routine analysis
1136	6.2	33.6	Unknown	
1137	11.2	8.7	BPH	Adenomatous hyperplasia, focal atypia
1138	11.7	120	Metastatic-P	Adeno CA; T3M1b, strontium therapy
1139	4.9	9.6	Cancer-P	Adeno CA; 3-y ago; prostatectomy
1140	10.5	317	Metastatic-P	Osteoblastic metastasis; chemotherapy
1141	14	31.7	Metastatic-P	Adeno CA; M1b, chemotherapy
1142	14.2	12	Cancer-C	Colon well diff. adeno; M0; BPH
1143	14.5	0.2	Cancer-SQ	Squamous cell CA mouth; treated 1-m ago
1144	101	98	Unknown	
1145	13	43	Metastatic-P	Adeno CA;M1b, treated
1146	249	53.6	Metast.-P/L	Prostate& lung CA, Mx; progression
1147	13.3	0.4	Unknown	Serum routine analysis
1148	5.5	14.5	Cancer-P	Adeno CA; 2-y ago, treated
1149	6.3	30	Cancer-P	Well diff. adeno CA; prostatec. 1-m ago
1150	3.9	9.2	No tumor	Hypertension
1151	7	8.3	Unknown	
1152	192	45	Unknown	Acute renal failure; pure hypercholesterolemia
1153	10.8	14.9	Unknown	
1154	24	10.6	Unknown	COPD, elevated PSA
1155	7.5	2.7	No tumor	Testicular CA 30-y ago, no evidence of CA
1156	4.4	12	Unknown	
1157	7.5	15.4	Cancer-P	BPH; well diff. adeno; treated 10-m ago
1158	8.4	13	Cancer-P	Adeno CA 2-y ago; hormone therapy; orchiectomy
1159	57.6	7.4	Unknown	Elevated PSA
1160	21.3	1	Unknown	Renal rejection; hemodialysis

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
1161	7.3	14.4	Cancer-P	Adeno CA; treated 1-y ago
1162	11.7	6.2	Cancer-L	Well diff. squamous cell; treated 1-m ago
1163	13	106	Unknown	
1164	12	16.5	Unknown	
1165	181	19	Metastatic-P	Moderately diff.; T4aN2; untreated
1166	5.2	1.6	No tumor	Spondilosys, cardiomyopathy
1167	4.4	359	Unknown	
1168	9	215	Metastatic-P	T3,4b;M1bc; Chemo; osteobla. M, no change for 6 m
1169	182	207	Metastatic	Mod. diff. adeno; M1b, extensive; orchiectomy
1170	4.4	45	Unknown	
1171	18.3	9	Unknown	Hypothyroidism, coronary disease.
1172	37.6	34	Cancer-P/L	Prostate/bronchogenic CA, M0; treated
1173	12	56	Cancer-P	T2cM0; treated
1174	34	12	Cancer	Asbestosis; pleural thickening; suspicious for CA
1175	3.7	7.1	No tumor	Chronic prostatitis; BX suspicious for malignant cells
1176	5.4	86	Metastatic-P	M1b, Nx, extensive, osteoblastic, strontium therapy
1177	7.2	6.7	Metastatic-P	M1b, Nx, extensive; osteoblastic
1178	24.4	8.7	Cancer-P	Adeno CA prostate
1179	12.6	13.8	BPH/Lymp.	History of nodular lymphoma of head
1180	11	37	Unknown	
1181	5	13	Cancer-P	Well diff. adeno; T2a; prostatectomy 3-w ago
1182	161	10.3	Unknown	Post-total right knee arthroplasty; elevated PSA
1183	17	16	Unknown	Elevated PSA
1184	3.5	8.8	Unknown	Elevated PSA
1185	45	0.6	Cancer-L	Bronchogenic squamous cell CA; 4-y ago, recurrence
1186	24.3	6	Cancer-P	Adeno CA; T2M0; pleural effusion; heart failure
1187	7.6	6.6	Unknown	
1188	7.3	0.4	No tumor	Degenerative joint disease
1189	12.2	18.8	Unknown	Pulmonary emphysema
1190	37.2	0.8	Unknown	
1191	5	15.4	Unknown	BPH/ prostatitis
1192	13.6	49.6	Metastatic-P	M1b; multiple foci in bones; orchiectomy, chemo.
1193	6.2	0.2	Cancer-P	Adeno CA; T2; prostatectomy 2-y ago
1194	11	1.2	Metastatic-C	Diff. ade.; N5; colectomy 10-m ago; chemo; remission
1195	20.1	6.1	Cancer-C	Adeno CA; right hemicolectomy 7-y ago
1196	6.4	0.4	No tumor	Diabetes mellitus
1197	7.7	0.7	No tumor	Serum routine analysis
1198	8.3	ND	Cancer-C	Adeno Cecum 3-y ago; remission
1199	10	ND	Metastatic-C	Rectum adeno, M2c liver; surgery-chemo 2-w ago
1200	9.1	ND	Cancer-C	Adeno colon 3-y ago; hemicolectomy; chemo.
1201	9.1	5	Cancer-P/Lx	Adeno; T2M0;prostatectomy 6-m ago; Lx CA 4-y ago
1202	12.2	ND	Metastatic-C	Adeno cecum 1-y ago; N3M3c; colectomy/chemo.
1203	4.4	ND	Cancer-C	Sigmoid adeno; colectomy-chemo 3-m ago
1204	7	ND	Cancer-C	Adeno cecum 2-y ago; surgery/chemo; remission
1205	4.1	ND	Cancer-C	Rectum adeno 2-y ago; surgery/chemo; remission
1206	65.3	34	Unknown	
1207	332	10.3	Unknown	
1208	44.5	534	Metastatic-P	Adeno mod. well diff; T3N2M1c; TURP 11 days ago
1209	25	156	Cancer-P	Poorly diff.adeno; untreated
1210	3.8	14.6	Unknown	
1211	4.5	0.5	Unknown	
1212	8.5	8.4	Unknown	
1213	9.6	85	Cancer-P	Adeno CA; 3-y ago
1214	35	85.2	Metastatic-P	Adeno T3N3M0; post-chemotherapy
1215	3.5	0.6	Unknown	
1216	25.1	6.5	Unknown	
1217	8.9	6.1	No tumor	Congestive heart failure; chronic urinary infection
1218	5.2	11.5	Cancer-P	History of CA; treated; no evidence of metastasis

continued

Table II. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
1219	7.6	0.8	Unknown	
1220	4.8	67	Unknown	
1221	6.6	8.2	BPH	Hyperplasia, adenomatous; untreated
1222	4.2	16.3	No tumor	Congestive heart failure
1223	6.7	0.6	No tumor	Serum routine analysis
1224	6.8	6.6	No tumor	Serum routine analysis
1225	11	21	Unknown	Chronic prostatitis
1226	4.3	46	Unknown	
1227	30	0.6	Unknown	
1228	20	7	Metastatic-T	Papillary thyroid CA, N5Mthyroidectomy 9-m
1229	167	11.6	Unknown	Spinal cord injury
1230	6.5	17	Unknown	
1231	7	0.6	Cancer-B	TCCA bladder; 9-m; resected; no evidence of CA
1232	8	74.5	Metastatic-P	M1b, strontium therapy; progression
1233	10.1	9.6	No tumor	Benign hypertension
1234	72	32	Metastatic-P	Mod. well diff. Adeno; M1b, extensive; treated
1235	3.8	0.2	Cancer-P	Radical prostatectomy 3-y; M0; no evidence of CA
1236	5.3	6.2	Cancer-P	Well diff. adeno CA; treated
1237	103	154	Cancer-P	Poorly diff.; RT renal obstruction; T3aN5; untreated
1238	10	6.6	Unknown	
1239	31.1	0.2	Cancer-Leu	Chronic myeloid leukemia
1240	5.3	10.1	Unknown	
1241	50.4	28.4	Cancer-P	Adeno CA; TURP 2-y ago
1242	9.3	20	Cancer-P	Well diff. adeno, 7-m; T1cM0; treated
1243	9	1.6	No tumor	Hemiplegia
1244	4.8	24	Unknown	Possible BPH
1245	6	16	CA-P/BPH	BPH; T1a; incidental finding, well diff. M0N0

showed that: (i) the intra-assay precision was <12%; (i) the inter-assay precision was <13%; and (iii) the sensitivity, or minimal detectable dose, was approximately 2 ng/mL.

Expected values. The relative distribution of MPS-1 concentrations in healthy individuals, patients with various types of active cancer, and patients with non-malignant diseases is presented in Tables II to XIV, and also illustrated graphically from data extracted from each Table (II to XIV), to facilitate interpretation of the results for cancer patients in stable conditions, in progression, or remission, which is not possible to easily deduce from simply examining the numerical tables with fully processed data alone.

Healthy individuals: The results of studies with healthy individuals indicate an MPS-1 reference range for adults (<70 years) of non-detectable to 10 ng/mL (98%) of the healthy population). A total of 2% of this group had MPS-1 levels in the range of 10.01-20.0 ng/mL (designated as the intermediate grey area because of significant overlapping with both active cancerous disease and non-malignant conditions at this range. Tables II to XIV show the plots and the range levels corresponding to various types of cancer. There was no significant difference in MPS-1 levels between female (19-70 years) and male (21-88 years) healthy individuals.

Biological and physiological characteristics of MPS-1 in human normal and malignant tissues and serum as detected with polyclonal antibodies against MPS-1 (AA 2-17 peptide) and methods to detect apoptosis. To initially illustrate the characteristics of MPS-1 as a tumor marker, a few examples are presented in the following section before the extensive analysis of the serum samples of individual patients are presented in Tables II to XIV.

Presence of MPS-1 in syncytiotrophoblasts (SY) and its release into the blood of pregnant women (Figure 2). Syncytiotrophoblasts are multinucleated cells found in the placenta of embryos. They are the outer syncytial layers of the trophoblasts and actively invade the uterine wall and blood vessels. In this sense they behave as invasive cancer cells. Cells from the syncytiotrophoblasts secrete MPS-1 in the blood vessels of pregnant women and thus, MPS-1 can be detected in the circulation. Figure 2A shows SY stained with anti-MPS-1 antibodies, while Figure 2B shows anti-

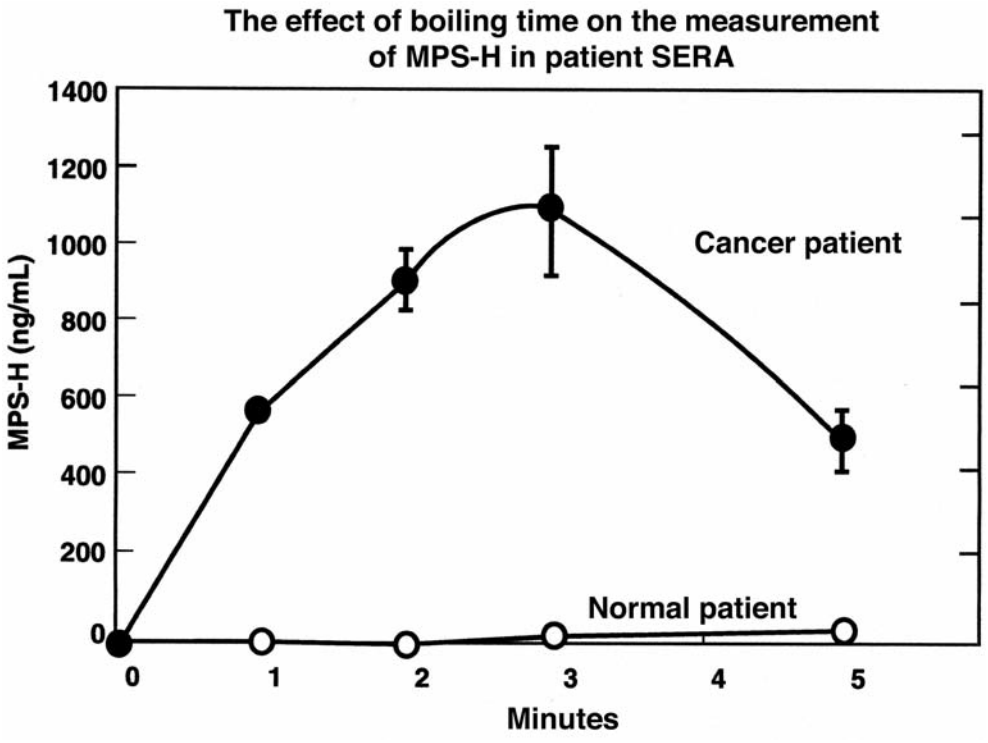


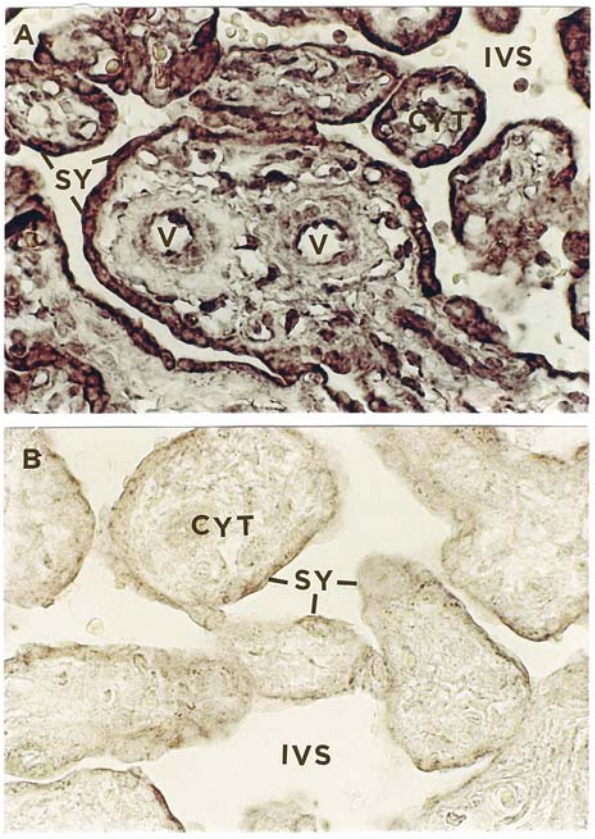
Figure 1. *The effect of boiling time on the measurement of MPS-1 in patient's serum. MPS-H, heat-activated MPS-1 protein in the serum. The serum samples were boiled to 100˚C for the times indicated in the abscissa. Ordinate, ng/mL of released MPS-1 protein from the serum after heat treatment.*

MPS-1 antibody neutralized by 100-fold peptide A (2-17 domain of MPS-1), showing neutralization of the antibody staining, indicating specificity. Figure 2C, bottom chart, shows that the MPS-1 level in the serum measured by RIA, of five separate healthy pregnant women increases in a time-dependent fashion with the 1st, 2nd and 3rd trimester, of pregnancy as the syncytiotrophoblast progressively invades the uterus.

MPS-1 identified by immunoblot studies in serum of a cancer patient, and in serum of a healthy individual with no evidence of cancer (Figure 3A). The serum was obtained from a patient with metastatic cancer. Peaks 4 and 5 correspond to MPS-1 [4], and peak [5] to a degradation product of MPS-1. The serum of the normal individual (peaks [4] and [5]) barely show the MPS-1 peaks. Proteins denoted [1, 2 and 3] are serum carriers for MPS-1 protein in both Figure 3A and B. Proteins [6, 7 and 8], have been previously identified as HPHU-2, HPHU-1, and C3a [Anaphylotoxin] (6). Figure 3C. Peaks [1 to 6] are molecular weight markers.

Analysis of superficially spreading malignant melanoma to adjacent tissues indicate induction of apoptosis by melanoma cells which illustrates the origin of MPS-1 in the serum of patients, illustrating the origin of MPS-1 in serum of patients with cancer (Figure 4). Figure 4A, shows melanoma cells stained for MPS-1 (red stain). Figure 4B, corresponds to an adjacent section of Figure 4A, processed to detect apoptosis (brownish/black stain). The brownish/black stain indicates nucleus fragmentation of DNA which shows initiation of apoptosis in the melanoma cells. Figure 4C is a 3D computer tomographic reconstruction, of alternative and adjacent melanoma cells and apoptotic cell tissue sections, with increased levels of MPS-1 (Red stain), and apoptosis of adjacent keratinocytes (Black stain). About one-hundred alternative and consecutive slices were stained for MPS-1 and apoptosis. The sections were alternatively stained with: (i) anti-MPS-1 antibodies (AA 2-17 peptide, and (ii) processed for apoptosis by detecting DNA fragments.

MPS-1 expression and apoptosis in benign nevi. Figure 5A shows the MPS-1 staining pattern in benign nevi, which shows intensely positive superficial type A melanocytes (24). The apoptosis staining pattern (Figure 5B) is observed as a gradient, opposite to the MPS-1 gradient, from intensely positive in deep areas of the skin to negative in surface areas. Figure 5C is a 3D tomographic reconstruction of



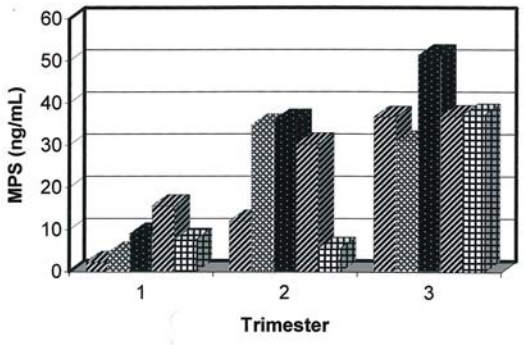


Figure 2. *MPS-1 is expressed in placenta and released into the blood by the invasion of the uterine wall by syncitiotrophoblasts cells during healthy pregnancy in a time-dependent fashion. (A) histochemistry of placental cells labeled with anti- MPS-1 antibodies; (B) MPS-1 neutralized with MPS-1 peptide 2-17 which prevents staining, showing specificity; (C) bottom, five separate healthy pregnant women progressively increased the MPS-1 level in the 1st, 2nd and 3rd trimester of pregnancy.*

tissue slices corresponding to slices alternatively stained for MPS-1 (red stain) and apoptosis (B, black stain), which is in a gradient from intensely positive superficial type A melanocytes (MPS-1, red stain) to negative type C (black, apoptosis).

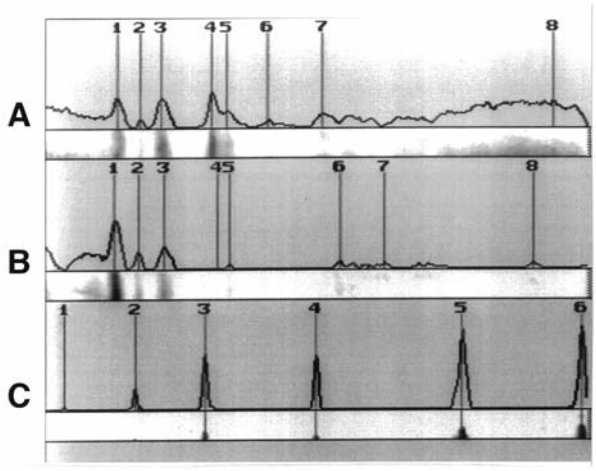


Figure 3. *MPS-1 identified by immunoblot studies in sera of cancer patients with anti-MPS-1 antibodies (AA 2-17); (A) the serum was obtained from a patient with metastatic cancer. Peaks 4 and 5 correspond to MPS-1 (4 is the major peak of 9.8 kDa; a degradation product of MPS-1 is also detected, Peak 5). As can be seen the serum of a normal subject (B), peaks 4 and 5) barely shows the MPS peaks. Proteins denoted 1, 2 and 3 are serum carriers for MPS-1 proteins in both A and B. Proteins 6, 7 and 8 have been previously identified as HPHU-2, HPHU-1, and C3a [Anaphylotoxin] (Ref. 6). (C) Peaks 1 to 6 are molecular weight markers. Note the very low levels of MPS-1 in B, normal serum.*

Measurement of MPS-1 in serum of healthy individuals and in patients with different types of malignant and benign tumors. In a series of experiments with about 1200 patients, the data showed the general distribution of MPS-1 values for active cases of cancer disease (clinical evidence of disease progression). Initially we found that 85% of the patients in this group showed MPS-1 levels in the range of 20 to >50 ng/mL. In 9% of the individuals in this group, the MPS-1 levels ranged from 10.01 to 20 ng/mL (intermediate "grey area"). Thus, elevated MPS-1 levels identified patients with active malignant tumors with at least 80% confidence limits (14-17). It is interesting to note here that in patients with metastatic cancer of various origins, such as prostate and colon, the MPS-1 levels were in most instances (>75% of the cases) extremely high (100 to 1000 ng/mL). Non-malignant diseases: The combined results for all nonmalignant diseases (*e.g.* liver cirrhosis, hepatitis C) indicate that 75% of the patients in this group had MPS-1 levels of <10 ng/mL. In 21% of the individuals in this group MPS-1 levels were in the area of 10.01 to 20 ng/mL (intermediate grey area). Only 1% of the patients with numerous other nonmalignant diseases (N=201) had MPS-1 levels of about 20 ng/mL or lower (N=2).

MPS-1 in sera of patients evaluated for cancer. Table II shows the measurement of circulating MPS-1 in sera of

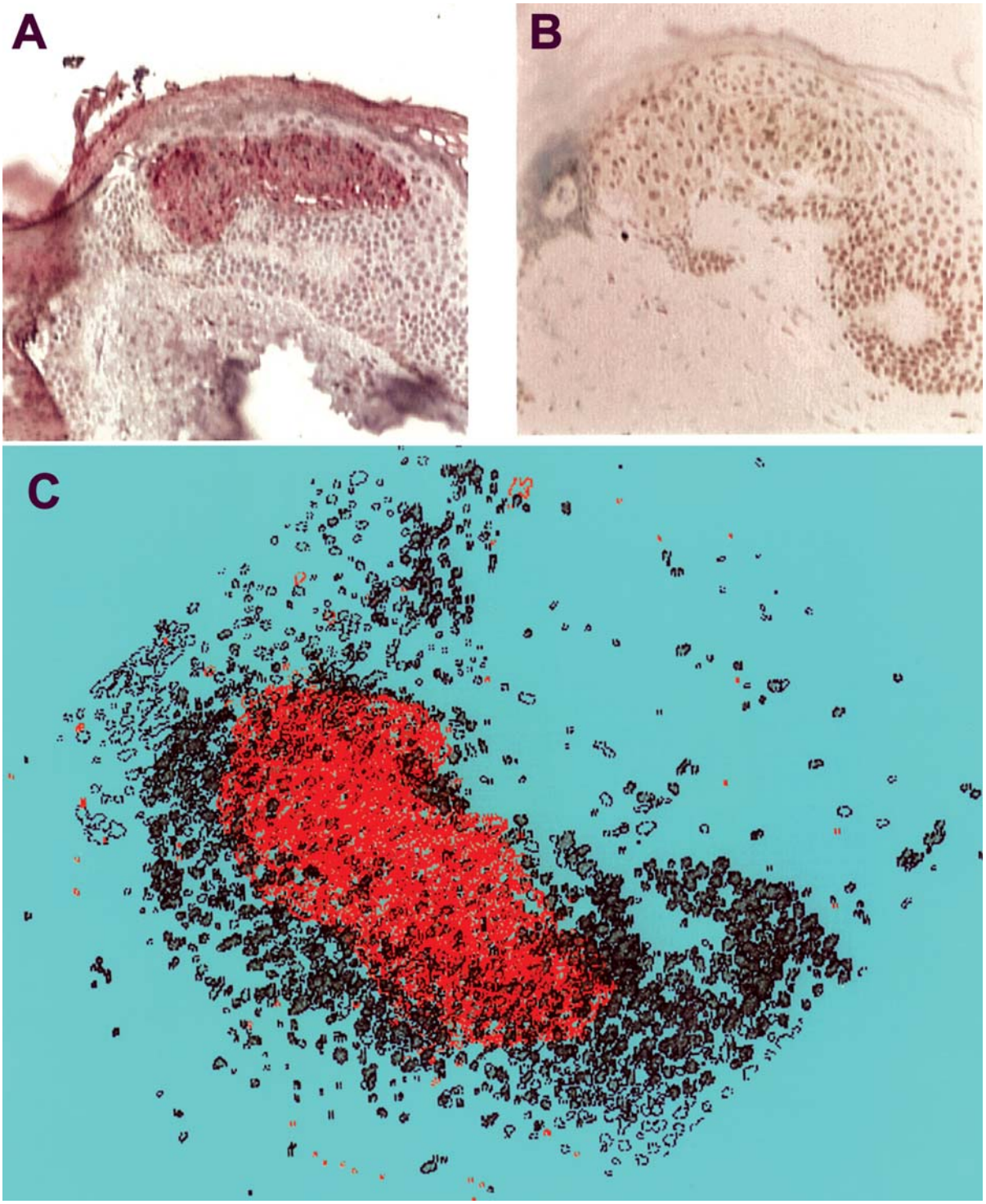


Figure 4. *Analysis of superficially spreading malignant melanoma to adjacent tissues indicate induction of apoptosis. A shows melanoma cells stained for MPS-1(red stain); B corresponds to an adjacent section of A processed to detect apoptosis (brownish/black stain). As can be observed, the dark nucleus indicates fragmentation of DNA which indicates initiation of apoptosis in the melanoma cells; C represents a 3-D computer reconstruction of melanoma cells with increased levels of MPS-1 (Red stain) which are aggressively phagocytizing adjacent melanoma cells, and also inducing apoptosis of adjacent keratinocytes (black stain). About 100 slices of a skin melanoma sample, superficially spreading, were sectioned and alternatively stained with (i) anti-MPS-1 antibodies (Red stain) and; (ii) processed for detection of apoptosis (black stain) which was detected by staining DNA fragments. Figure 4A shows staining with anti-MPS-1 antibodies and Figure 4B shows the apoptotic nuclei of keratinocytes surrounding melanoma cells. Figure 4C shows the 3-D reconstruction of this specimen. It was carried out by using a Jurassic Park Silicon Valley Computer.*

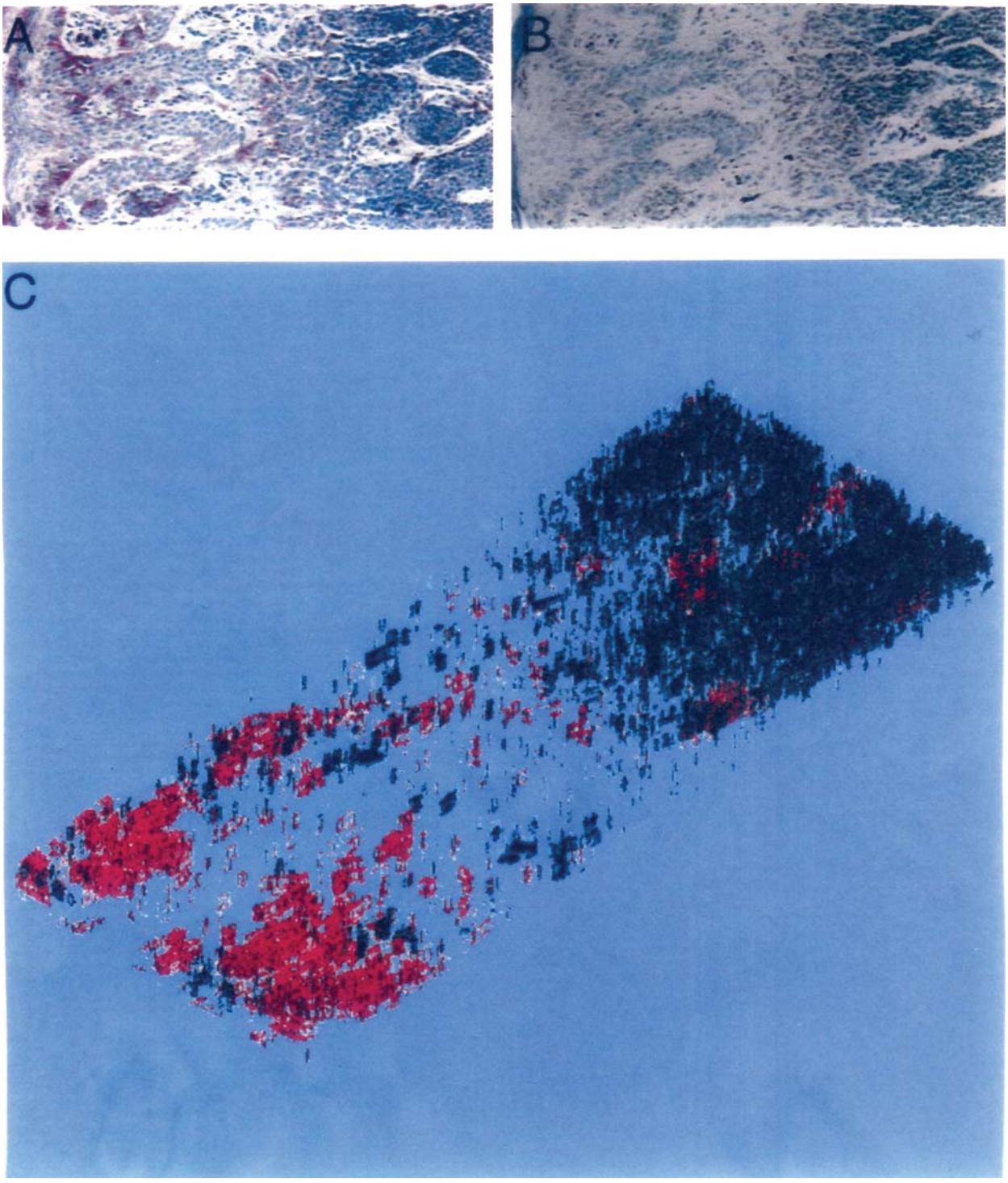


Figure 5. *MPS-1 expression and apoptosis in benign nevi. A: MPS-1 staining pattern of benign nevi is in a gradient from intensely positive superficial type A melanocytes (MPS-1, red stain) to negative type C (black staining, apoptosis). B: The corresponding apoptosis staining pattern is present as a gradient opposite to the MPS-1 gradient, from intensely positive in deep areas of the skin to essentially negative in surface areas. C: Reconstruction of the 3D structure was done utilizing the Jurassic Park Silicon Valley Computer.*

Table III. *Measurement of circulating MPS in sera of patients with nonmalignant diseases.*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
3	0.1	0.2	No tumor	Serum routine analysis
366	0.2	9.1	No tumor	Diverticulosis of colon
43	0.54	0.5	No tumor	Atrophic gastritis, gastroesophageal reflux
41	0.7	0.4	No tumor	Diabetes, general osteoarthritis
676	0.7	7.2	No tumor	Hypertension; esophageal dismotility
30	0.9	0.2	No tumor	Congestive heart failure, COPD, severe coronary arthery disease
42	1.02	1.1	No tumor	Bladder carcinoma, treated 12 years ago, no evidence of disease
40	1.1	0.6	No tumor	Aortic arteriosclerosis
686	1.3	0.7	No tumor	Insulin-dependent diabetes; hypotension.
721	1.3	30.5	No tumor	History of COPD
552	1.3	3.5	No tumor	Cardiac insufficiency
37	1.5	1	No tumor	Congestive heart failure, hypertension, COPD, hypercholesterolemia
50	1.5	2.3	No tumor	Alcohol abuse, peripheral neuropathy
678	1.5	0.3	No tumor	Status post left frontoparietal infarction
44	1.6	1	No tumor	Hypertension
68	1.6	1.3	No tumor	Degenerative changes, lower cervical spine
51	1.7	95.1	No tumor	Serum routine analysis
682	1.8	12.4	No tumor	History of duodenal ulcer; congestive heart failure
49	1.9	1.3	No tumor	Cardiomegaly
684	2	17.2	No tumor	Elevated PSA
690	2	0.9	No tumor	Serum routine analysis
283	2.3	ND	No tumor	Euthyroid
444	2.3	12.1	No tumor	Congestive heart failure, glaucoma
729	2.3	4.1	No tumor	No evidence of cancer
139	2.4	20	No tumor	Organic heart disease, arthritis, hypertension
86	2.5	100	No tumor	Iron deficiency anemia, serum routine analysis
673	2.5	12.4	No tumor	Arthritis; degenerative joint disease
406	2.7	54.7	No tumor	Elevated PSA
426	2.7	1.2	No tumor	Multyple cystic liver
725	2.7	14.7	No tumor	No evidence of cancer
196	2.9	1	No tumor	Coronary artery disease, calcified aorta, COPD, esophageal diverticula
278	3	16.2	No tumor	Hypertension, elevated PSA
500	3	10	No tumor	Arthritis
697	3	16.4	No tumor	Cardiomyopathy
23	3.1	6.5	No tumor	Blood routine, normal patient
26	3.1	0.9	No tumor	Verruca vulgaris, skin
288	3.1	ND	No tumor	Hypothyroid
329	3.1	ND	No tumor	Hypothyroid, hypertension, diabetes
1	3.2	1.8	No tumor	Cannabis S. abuse, macrocytic anemia
362	3.2	1.7	No tumor	Serum routine analysis
403	3.2	0.6	No tumor	Cardiac disease, hypertension
215	3.3	0.3	No tumor	Serum routine analysis
392	3.3	248	No tumor	Hypertension
299	3.4	ND	No tumor	Hyperthyroid, osteomyelitis, R-foot
717	3.4	4.1	No tumor	Insulin-dependent diabetes.
167	3.5	2.2	No tumor	No evidence of cancer.
405	3.5	0.6	No tumor	Emphysematous disease
420	3.5	ND	No tumor	Idiopathic cardiomyopathy; diabetes mellitus
526	3.5	12.5	No tumor	Rheumatic heart disease
544	3.7	1.3	No tumor	Anxiety disorder; otherwise normal patient
387	3.8	37.7	No tumor	Elevated PSA
456	3.8	9	No tumor	Serum routine analysis
716	3.8	21.5	No tumor	No evidence of cancer
66	3.9	2.2	No tumor	Cannabis Sativa abuse, alcohol dependence
664	3.9	12.4	No tumor	Arthritis; degenerative joint disease
71	4	0.7	No tumor	Sigmoid/descending colonic diverticulosis
73	4	2.3	No tumor	Diabetes, proliferative diabetic retinopathy
591	4	11.2	No tumor	Elevated PSA

continued

Table III. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
645	4	2.5	No tumor	Hypertension
239	4.1	0.8	No tumor	Serum routine analysis
292	4.1	ND	No tumor	Euthyroid, post-traumatic stress disorder, hypertension
312	4.1	1.9	No tumor	Serum routine analysis
435	4.1	1.4	No tumor	Hearing problem
92	4.2	1.1	No tumor	Status post coronary artery bypass graft
287	4.3	ND	No tumor	Hypothyroid, Grave's disease , treated with I-131
324	4.3	0.7	No tumor	Degenerative arthritis, hypertension, peptic ulcer
494	4.3	9.7	No tumor	Serum routine analysis, elevated PSA
707	4.3	ND	No tumor	Normal subject
477	4.4	ND	No tumor	Cholelitiasis, diffuse parenchymal liver disease
531	4.5	19.5	No tumor	Chronic prostatitis
568	4.5	16.9	No tumor	Diabetes; emphysema
425	4.7	15	No tumor	COPD, cardiopulmonary disease, alcohol abuse, hypertension
436	4.7	ND	No tumor	Liver cirrhosis, active hepatitis C
704	4.7	16.2	No tumor	Actinic keratosis
399	4.8	2.1	No tumor	Chronic peptic ulcer
421	4.8	14.8	No tumor	Pain medication
427	4.8	22.2	No tumor	Elevated PSA
327	5	0.7	No tumor	Serum routine analysis
354	5	0.5	No tumor	Diabetes
454	5	9	No tumor	Diabetes mellitus, mild renal insufficiency
649	5	59.7	No tumor	Hypertension; elevated PSA
698	5.2	15.4	No tumor	Prostatitis: chronic inflammation. Negative for malignancy
457	5.3	35	No tumor	Hypertension
352	5.4	0.6	No tumor	Aortic atherosclerosis, atrial fibrilation
300	5.5	ND	No tumor	Euthyroid
515	5.5	1	No tumor	Serum routine analysis
581	5.5	4	No tumor	Normal subject; DJK
696	5.5	0.4	No tumor	Diabetes
453	5.7	37	No tumor	COPD
521	5.7	2.2	No tumor	No evidence of malignant disease
528	5.7	29.6	No tumor	Congestive heart failure, CVA
245	5.8	0.1	No tumor	Emphysema, hypertension.
57	5.9	1.3	No tumor	Emphysema
534	5.9	11.4	No tumor	Chronic prostatitis
657	5.9	1.2	No tumor	Cardiomyopathy
235	6	0.8	No tumor	No rib fracture is noted
281	6	ND	No tumor	Euthyroid, alcoholic, post-traumatic stress disorder
532	6	9.5	No tumor	Status post CVA
627	6.1	11.2	No tumor	Serum routine analysis
472	6.2	5.3	No tumor	Serum routine analysis
654	6.2	ND	No tumor	Serum routine analysis
103	6.3	0.7	No tumor	Myocardial perfusion defect
138	6.3	0.5	No tumor	No evidence of pulmonary disease, or lung tumor
311	6.3	11.6	No tumor	Osteoarthritis
464	6.3	31.3	No tumor	Elevated PSA
518	6.3	17.4	No tumor	Elevated PSA, prostatitis
658	6.3	7.2	No tumor	Hypertension; esophageal dismotility
309	6.4	ND	No tumor	Euthyroid
445	6.5	6.4	No tumor	Pulmonary tuberculosis, extensive; no tumor; diabetes mellitus; COPD
91	6.6	0.6	No tumor	Mild degenerative joint disease
529	6.6	12	No tumor	Serum routine analysis
693	6.6	1.4	No tumor	No evidence of cancer
204	6.8	0.4	No tumor	Repaired hydrocele, no malignancy, diabetic, chronic renal failure
587	6.8	0.6	No tumor	Diabetes; arteriosclerotic heart disease
423	6.9	20.1	No tumor	Urinary infection, retention
432	6.9	0.8	No tumor	Malignant neoplasia of bladder treated 6 y ago. No evidence of cancer

continued

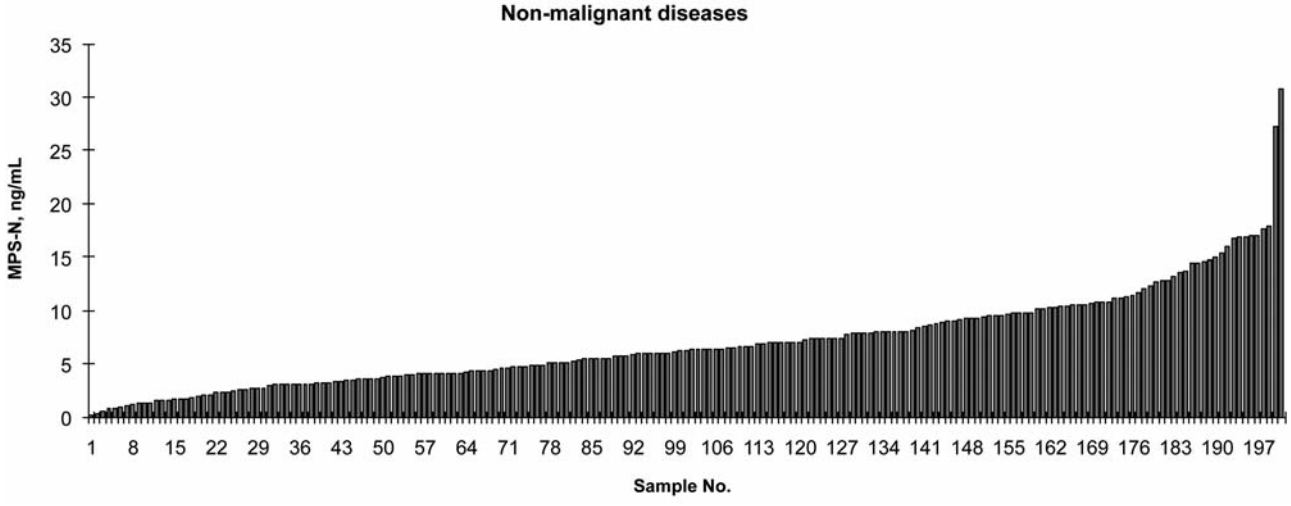
Table III. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
710	6.9	0.6	No tumor	Diabetic; foot infection
19	7	31	No tumor	Chronic obstructive pulmonary disease
180	7	24	No tumor	Prostatic needle biopsy, negative for malignancy
449	7	14.4	No tumor	Coronary artery disease
626	7.2	1.5	No tumor	Aortic arteriosclerosis
259	7.3	ND	No tumor	Alcoholic cirrosis of liver, end stage, 300 pound patient, AFP 15,767
495	7.3	9.4	No tumor	Serum routine analysis, elevated PSA
511	7.3	1.4	No tumor	No evidence of disease
31	7.35	1.2	No tumor	Cardiomyopathy, diabetes type II, reumatoid arthritis, artheriosclerosis
270	7.4	7	No tumor	Malignant hypertension, emphysema, COPD, heart failure
320	7.4	ND	No tumor	Euthyroid, cardiomegaly
346	7.7	2.7	No tumor	Hypertension, diabetes, congestive heart failure
319	7.8	ND	No tumor	Euthyroid, depression
358	7.8	0.3	No tumor	Schizophrenic
530	7.8	1.2	No tumor	Thyroid nodules, heroin-cocaine-alcohol depencence
538	7.8	17.4	No tumor	Elevated PSA, prostatitis
102	8	0.2	No tumor	Diabetes, benign hypertension, alcohol abuse
237	8	1.1	No tumor	Left carotid endarterectomy, serum routine analysis
439	8	6.3	No tumor	Calcified granuloma R lung, smoker
450	8	6.8	No tumor	Benign hypertension
623	8	2.3	No tumor	Sigmoid colon diverticulosis
662	8	1.3	No tumor	Myocardial ischemia
462	8.1	10	No tumor	Serum routine analysis
304	8.3	ND	No tumor	Euthyroid, rheumatoid artritis
321	8.5	0.6	No tumor	Serum routine analysis
193	8.6	27.4	No tumor	Pain in left shoulder, normal X-ray, elevated PSA
602	8.7	0.2	No tumor	Diverticulosis of colon; hypertension
564	8.9	2.3	No tumor	Arthritis
243	9	0.8	No tumor	Left foot infection, gangrene, necrosis, multiple kidney cysts
415	9	1.2	No tumor	Benign hypertension
177	9.1	2.2	No tumor	COPD, atherosclerosis
720	9.2	4.3	No tumor	Low back pain; no evidence of cancer
249	9.3	1.1	No tumor	Hypertension
316	9.3	2.3	No tumor	Serum routine analysis
718	9.4	10.2	No tumor	Insulin-dependent diabetes; hypertension. Diverticulosis of colon.
260	9.5	32.9	No tumor	Status post-kidney transplant, hepatitis B, elevated PSA
334	9.5	ND	No tumor	CEA: 420; bilateral calcified lung granulomas
409	9.5	ND	No tumor	Gallbladder with gallstone disease
548	9.6	29.6	No tumor	Congestive heart failure, diverticulosis; COPD
282	9.7	ND	No tumor	Euthyroid
395	9.8	1.6	No tumor	Status post-hip replacement
555	9.8	9	No tumor	Diabetes, gastritis
610	9.8	7.4	No tumor	Cardiomegaly
114	10.1	1.6	No tumor	Osteoarthritis, diffuse idiopathic skeletal hyperostosis
599	10.1	1.4	No tumor	Serum routine analysis
584	10.2	0.1	No tumor	Diabetes
221	10.3	0.4	No tumor	Rheumatoid arthritis
308	10.4	ND	No tumor	Euthyroid
525	10.4	12.5	No tumor	Benign hypertension
669	10.5	0.5	No cancer	Patient with polyclonal gammopathy; no evidence of cancer; diabetes
369	10.5	52.7	No tumor	Elevated PSA
681	10.5	1.6	No tumor	Serum routine analysis
478	10.6	1.4	No tumor	Status post-liver transplant
488	10.7	1	No tumor	Renal vascular disease
123	10.8	0.2	No tumor	Coronary artery disease, hypertension, Pernicious anemia, Hepatitis C
262	10.8	3.2	No tumor	Benign hypetension, hepatitis
95	11.1	1.7	No tumor	Diabetes, hypertension

continued

Table III. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
491	11.1	10.2	No tumor	Osteoarthritis, generalized
314	11.3	2.7	No tumor	Serum routine analysis
536	11.4	1.8	Ulcer	Peptic ulcer disease; diabetes mellitus type II
241	11.7	0.8	No tumor	Serum routine analysis
388	12	7	No tumor	Serum routine analysis
119	12.3	0.4	No tumor	Aortic valve sclerosis with severe cardiac dysfunction
182	12.6	6.1	No tumor	Presenile dementia
340	12.8	ND	No tumor	Hyperthyroid, schizophrenia, COPD
422	12.8	1	No tumor	Diabetes mellitus
379	13.2	18.2	No tumor	
266	13.5	2.6	No tumor	Hypertrophy of kidney, Paget's disease, schizophrenia
573	13.7	1.7	No tumor	Degenerative joint disease
579	14.4	1.4	No tumor	Tobacco abuse
701	14.4	0.6	No tumor	Serum routine analysis
519	14.6	4.9	No tumor	Coronary artery disease
634	14.7	ND	No tumor	Chronic gastric inflammation
386	14.9	1.5	No tumor	Coronary artery disease, alcohol abuse
694	15.3	11	No tumor	Hypertension
404	16	12	No tumor	Cardiac disease, hypertension
702	16.7	0.5	No tumor	Serum routine analysis
98	16.8	4.6	No tumor	Schizophrenia, neumonia, no evidence of pulmonary malignancy
655	16.8	9.1	No tumor	Serum routine analysis
570	16.9	3.4	Ulcer	Diverticulosis of colon; stomach ulcer
484	17	7.5	No tumor	Marked degenerative arthritis
688	17.6	15.4	No tumor	Cardiomyopathy
560	17.8	1.6	Ulcer	Duodenal ulcer
533	27.2	2.4	Ulcer	Large duodenal ulcer, 1.8 cm with active proliferative border
651	30.8	1.3	Ulcer	Gastric ulcer



patients evaluated for cancer. In this series 1245 patients were tested. The results of studies with healthy individuals indicate a MPS-1 reference range for adults (Table II; 19-88 years) of non-detectable to 10 ng/mL (82% of the healthy population). In 17% of the individuals in this group MPS-1 levels were in the range of 10.01-20 ng/mL, denoted the gray area, because of the significant overlapping with both active cancerous disease and non-malignant conditions at this range level. In the following Tables (III to XIV) the patients shown are divided by type of tumor. Table II was used to initially

Table IV. *Measurement of circulating MPS in sera of patients evaluated for BPH.*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
665	1.7	28	BPH	Prostate: Glandular hyperplasia, atypical
402	2.2	23.3	BPH	BPH untreated
219	2.8	0.9	BPH	BPH untreated
394	3.4	10	BPH	Hyperplasia, adenomyomatous
353	4.1	21.7	BPH	Prostate hyperplasia, adenofibromyomatous, needle biopsies
201	4.4	90.7	BPH	BHP diagosed 3 years ago
659	4.7	16.5	BPH	Prostate: glandular hyperplasia; chronic inflammation
442	5	4.9	BPH	Prostatic hyperplasia, chronic inflammation
431	5.1	16	BPH	BPH
566	5.3	48.5	BPH	Hypertension
75	6.3	33.2	BPH	Glandular hyperplasia, dysplasia, atrophy, no evidence of malignancy
416	7	0.2	BPH	Chronic atrial fibrillation; heart failure
107	7.5	33.2	BPH	Biopsies, negative for PC, prostatic displasia, glandular hyperplasia
437	8.1	6.3	BPH	Hyperplasia, adenofibromatosis, 6 m ago
467	8.8	14	BPH	BPH
660	9.7	8.4	BPH	Prostate: nodular hyperplasia
317	9.9	17.4	BPH	Kydney cancer, status post L nephrectomy, no evidence of disease
212	10.4	21.5	BPH	BHP, untreated
501	10.8	8	BPH	Hyperplasia, dysplasia
551	11	33.8	BPH	BPH
474	11.3	5.4	BPH	Hyperplasia, glandular
613	11.4	18.2	BPH	Hyperplasia, glandular; inflammation
493	12	10.2	BPH	BPH confirmed by needle biopsy, focal atypia present
414	12.1	1.2	BPH	Status post-cerebral bleed; hypertension
141	12.3	166	BPH	Hyperplasia of prostate
545	12.8	15.1	BPH	Diabetes; bronchitis
443	14	7	BPH	BPH, chronic stomach inflammation
571	14.6	41.7	BPH	Hyperplasia glandular
561	16.5	41.9	BPH	Serum routine analysis
238	19	21.8	BPH	Hyperplasia, squamous metaplasia
622	19.3	11.1	BPH	Prostate: glandular hyperplasia
410	24	4.1	BPH	Prostatic needle biopsy: hyperplasia, glandular
83	31	31.3	BPH	BPH, untreated
78	31.2	15.6	BPH	Prostate hyperplasia, glandular, needle biopsy, untreated
463	32	29	BPH	Prostatitis
348	36	1.5	BPH	Psycogenic polydipsia, COPD, tobacco abuse
135	50.4	40.6	BPH	BPH, glandular, diagnosed 6 month ago, serum routine analysis
390	0.7	4.8	BPH-T	Hyperplasia, adenofibromyomatous; TURP 5 m ago
429	2.1	1.4	BPH-T	BPH on Proscar
438	2.3	4.1	BPH-T	Prostatitis, Hyperplasia, glandular inflammation, TURP, 1 m ago
22	3	7	BPH-T	Prostatic hyperplasia, glandular, inflammatory, TURP
242	3.1	12.1	BPH-T	Hyperplasia, glandular, TURP 9 months ago
24	3.3	6.3	BPH-T	Prostatic hyperplasia, glandular, inflammatory, TURP
295	4.1	3.4	BPH-T	EUTHYROID, mild prostatic hyperplasia, treated
198	4.4	1.4	BPH-T	TURP 1 year ago, normal patient
67	5.2	1.1	BPH-T	TURP, serum routine analysis
54	6	0.5	BPH-T	Hyperplasia of prostate, TURP
13	15	0.8	BPH-T	Prostatic hyperplasia, TURP

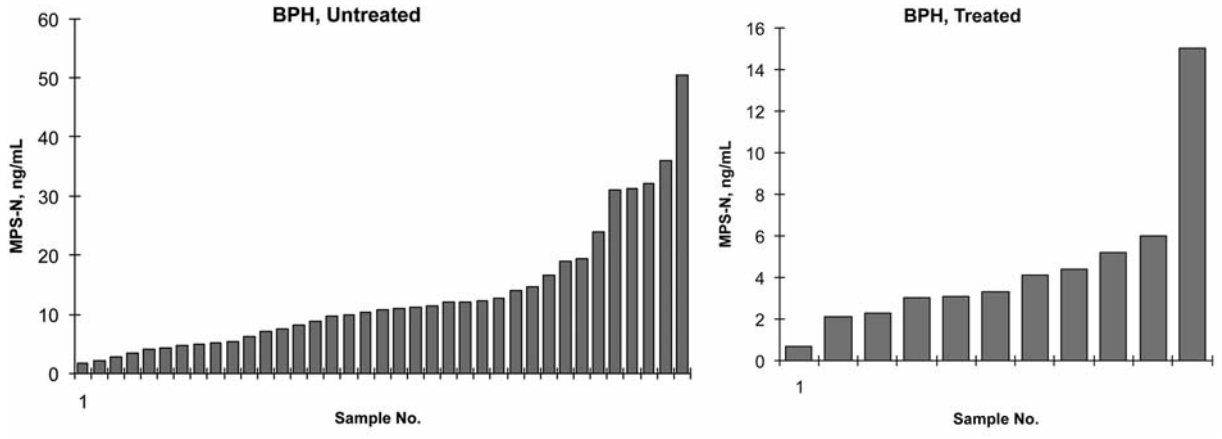


Table V. *Measurement of circulating MPS in sera of patients evaluated for prostate cancer.*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
20	1	18.3	Cancer P-RM	PC well diff., T3, radiation therapy
216	2.3	0.2	Cancer P-RM	PC well diff., T1/N0/M0, status post-radical prostatectomy, remission
338	2.3	0.2	Cancer P-RM	PC , T1N0M0, prostatectomy, end stage liver disease, high ferritin
208	2.5	37	Cancer P-RM	PC T2, treated, no evidence of metastatic disease
200	2.6	0.4	Cancer P-RM	PC well diff., TURP 6 years ago, no evidence of disease
569	2.6	15.7	Cancer P-RM	Well diff. adeno CA; T1cM0; treated
337	3.3	0.3	Cancer P-RM	PC well diff., T3bN0M0, prostatectomyn 2 m ago
34	3.45	46.7	Cancer P-RM	PC poorly diff., T1c, identified by needle biopsy, TURP
220	3.5	40.8	Cancer P-RM	PC poorly diff., T2a/N0/M0, resected 6 months ago, remission
25	3.6	1.4	Cancer P-RM	Chronic prostatitis with focal well diff. adenocarcinoma, TURP
556	3.8	19.5	Cancer P-RM	Pooly diff. Adeno CA; T2a/M0; treated 2-month ago
540	4.3	12.8	Cancer P-RM	PC well-diff. adeno-CA treated 10 months ago, T3M0
45	4.6	68.2	Cancer P-RM	PC moderately diff, T3/M0, TURP, hormonal therapy
332	4.7	26.6	Cancer P-RM	PC well diff., T3aM1b, treated 3 y ago, marked improvement, remission
63	4.8	29	Cancer P-RM	PC moderately diff., no metastasis, treated
384	5.1	0.6	Cancer P-RM	PC status post resection 5 y ago. No evidence of PC
671	5.1	15.7	Cancer P-RM	Focal squamous adeno CA of prostate; treated 6-month ago
202	5.4	0.2	Cancer P-RM	PC T3a, prostatectomy, radiation , 2 y ago; CoCA treated 7 y ago
65	5.4	28.6	Cancer P-RM	PC well diff., no metastasis, TURP
145	5.4	100	Cancer P-RM	PC, treated, serum routine analysis
62	5.6	27.8	Cancer P-RM	PC moderately diff.,no metastasis, radiation therapy
330	5.8	18.9	Cancer P-RM	PC well diff., T2M0, prostatectomy 7 m ago
562	6.1	15.7	Cancer P-RM	Well diff. adeno CA; T1cM0; treated
603	6.3	9	Cancer P-RM	PC treated 8-month ago
246	6.4	58	Cancer P-RM	Prostate cancer, treated 1 year ago, no evidence of metastasis
218	6.5	1.8	Cancer P-RM	PC well diff., T1/N0/M0, status post -prostatectomy, remission
347	6.8	21.2	Cancer P-RM	PC well diff., T1cM0, treated
313	7.1	18	Cancer P-RM	CA prostate, T3/M0, treated 6y ago, remission; diverticulosis of colon
401	7.2	1.2	Cancer P-RM	PC resected 2y ago
224	7.5	41.3	Cancer P-RM	PC poorly diff., T2a/N0/M0, TURP 6 months ago, remission
539	7.6	5	Cancer P-RM	PC well-diff. adeno-CA treated 1 y ago; T3M0
323	7.8	35.5	Cancer P-RM	PC well diff., T2M0, resected 6 m ago, remission
344	8	0.2	Cancer P-RM	PC treated 5 y ago, no evidence of disease
644	8	5	Cancer P-RM	84-y old with prostate adeno CA; radiation therapy
706	8	15.3	Cancer P-RM	Adeno CA prostate 2-y ago; T2cM0; TURP; hormone therapy
465	8.2	18.4	Cancer P-RM	PC well diff., T1c/M0; treated 5 m ago
213	8.5	0.2	Cancer P-RM	PC well diff.T2c/N0/M0, radical prostatectomy 6 month ago
64	9	41.1	Cancer P-RM	PC moderately diff., no metastasis, treated
490	9.3	0.6	Cancer P-RM	Status post-resection 5 y ago
468	9.3	3.7	Cancer P-RM	PC focal well diff. treated 5 m ago; stage I Hodgkin's disease, treated
621	10	16.1	Cancer P-RM	Prostate CA; treated
110	10.3	0.2	Cancer P-RM	PC, status post-radical retropubic prostatectomy
458	10.3	9	Cancer P-RM	PC well diff., TURP 1 y ago, remission
656	11.5	43.3	Cancer P-RM	Well diff. adeno CA; T2M0, treated
703	11.6	28.8	Cancer P-RM	Poorly diff. Prostate CA; T4aM0; TURP 6-m ago; remission
559	11.9	15.5	Cancer P-RM	PC Well diff., resected 7-month ago; T2cM0
150	12	0.2	Cancer P-RM	Prostatic malignancy, treated, serum routine analysis
485	12.5	12.1	Cancer P-RM	PC treated 1.5 y ago
232	13.2	64	Cancer P-RM	Well diff. adeno CA; T1c.
510	13.8	11.5	Cancer P-RM	PC poorly diff., treated 2 y ago; T2a/M0
203	14.1	24	Cancer P-RM	PC T3a, prostatectomy, radiation, 3 y ago; serum routine analysis
226	14.1	34	Cancer P-RM	PC well diff., T2c/N0/M0, resected 3 monts ago, radiation therapy
188	15	24.7	Cancer P-RM	PC poorly diff., T2, status post TURP
248	23.2	18.5	Cancer P-RM	PC 3 years ago, remission, M1b, marked improvement, no new lessions
679	4.7	244	Cancer P	TURP 4-y ago; serum routine analysis: elevated PSA
428	5.3	58.5	Cancer P	History of PC, serum routine analysis
8	8.1	210	Cancer P	PC well diff., T3a/M0, no treatment
597	11.4	29.4	Cancer P	Well diff. adeno CA; T1cM0
7	15.4	112	Cancer P	Hyperplasia, adenocarcinoma, adenofibroma
550	16.1	47.5	Cancer P	PC well diff. ; hormonal therapy; M0
77	17	15.2	Cancer P	PC, untreated
60	18.5	45.9	Cancer P	PC, no metastasis
680	19.3	14.1	Cancer P	PC: Poorly diff. adeno CA; T3aM0; treated 3-y ago
612	20.4	53.5	Cancer P	Serum routine analysis

continued

Table V. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
74	21	64.6	Cancer P	PC
124	21	98.3	Cancer P	PC poorly diff., T3a, no metastasis, resected, serum routine analysis
263	21.1	16	Cancer P	Well diff. adeno CA of protate; T2a
256	21.4	51.4	Cancer P	PC no treatment, T2b
16	22.2	122	Cancer P	PC well diff., T1c, untreated, history of lung carcinoma, resected
497	24	16.4	Cancer P	PC well diff., hyperplasia, T2b
280	27	62.7	Cancer P	PC, unverified
252	28	24.7	Cancer P	PC well diff., T2b/N0M0, diagnosed 5 months ago, no surgery, follow up
79	28.2	84.6	Cancer P	PC poorly diff.
385	28.2	436	Cancer P	PC T4, resected 3 y ago
459	29.1	30.1	Cancer P	PC focal, T1c/M0
336	30	534	Cancer P	PC well diff., T3M0, treated 6 m ago
722	30.1	32.3	Cancer P	Adeno CA of prostate; T1cM0; untreated
389	30.2	840	Cancer P	PC, T2M0, untreated
269	30.3	17.3	Cancer P	PC well diff., treated, T2/M0, Hodgkin's disease, stage I
433	30.6	23	Cancer P	PC treated
130	30.6	85.5	Cancer P	PC well diff., no metastasis, Hodgkin's disease
168	32.2	5.2	Cancer P	PC, treated 3 years ago; serum routine analysis
620	32.4	0.4	Cancer P	Hystory of prostate cancer; hormonal treatment
589	32.7	15.2	Cancer P	Serum routine analysis
479	32.8	39	Cancer P	PC well diff. , T1c/M0; orchiectomy
483	33	279	Cancer P	Adenocarcinoma, T3/M0
471	33	326	Cancer P	PC well diff., untreated
106	33.2	34	Cancer P	PC well diff., untreated
160	33.4	45	Cancer P	Prostatic malignancy, treated, serum routine analysis
502	33.7	36.5	Cancer P	72 y old with history of PC and radiation therapy; T3/M0
506	33.7	18	Cancer P	Elevated PSA
129	34	17.6	Cancer P	PC well diff., resected, hormonal therapy
90	34.2	0.2	Cancer P	PC, stage B-II, status post-radical retropubic prostatectomy
104	36	44.8	Cancer P	PC moderately well diff., no metastasis, T2b
228	36	34	Cancer P	Well diff. adeno CA of prostate; T3aN2
251	36.2	1	Cancer P	PC well diff. , T2c, N0M0, radical prostatectomy,
351	36.2	43.4	Cancer P	PC, T3aM0, untreated
371	36.3	64.7	Cancer P	PC treated
377	36.6	18.2	Cancer P	PC well diff., T4 M0, TURP hormone therapy
94	37.2	1.7	Cancer P	PC, prostatectomy 11 years ago, serum routine analysis
672	40	85.3	Cancer P	Prostate: T3a; Bladder: transitional cell CA ; resected 2-y ago
117	42	0.4	Cancer P	PC , TURP performed 5 years ago, serum routine analysis
136	42	44	Cancer P	PC moderately well diff., T3a, no metastasis
328	42	19.4	Cancer P	PC well diff., T2M0, prostatectomy 6y ago, hormonal treatment
349	42.5	69	Cancer P	PC treated 6 y ago, recurrence
357	44.1	225	Cancer P	PC, large bilateral pleural effusions
279	45	6	Cancer P	PC well diff., 6 m ago, T2bM0, treated
520	45.5	58	Cancer P	PC, M0
174	45.6	46	Cancer P	PC , TURP
76	47.1	33.8	Cancer P	PC well diff., no evidence for metastasis
121	48.3	70	Cancer P	PC moderately diff.
451	48.4	10.5	Cancer P	PC T4a; treated 2 y ago,status post radiation therapy and orchiectomy
343	52	69	Cancer P	PC treated 3 y ago
363	52.5	12.4	Cancer P	PC untreated
112	53.4	60	Cancer P	PC, T1c, untreated
572	54	12	Cancer P	Well diff. adeno CA; T3; treated.
132	56.4	0.8	Cancer P	PC, post TURP, serum routine analysis
595	56.8	22.4	Cancer P	Patient with history of prostate cancer
195	61.2	23.6	Cancer P	Malignant neoplasia of prostate diagnosed 3 years ago
361	62.5	5.4	Cancer P	PC well diff., treated
661	67	40.1	Cancer P	History of prostate CA.
585	69.2	37.3	Cancer P	Poorly diff. adeno CA
374	73.2	0.2	Cancer P	PC treated, 5 y ago
486	76	13.5	Cancer P	PC treated 6 y ago
674	76	135	Cancer P	PC orchiectomy; hormonal therapy; M0
146	76.2	195	Cancer P	PC, no metastasis found
258	79	331	Cancer P	PC untreated
147	82.5	50.2	Cancer P	PC, Multiple sclerosis, Parkinson's disease, serum routine analysis

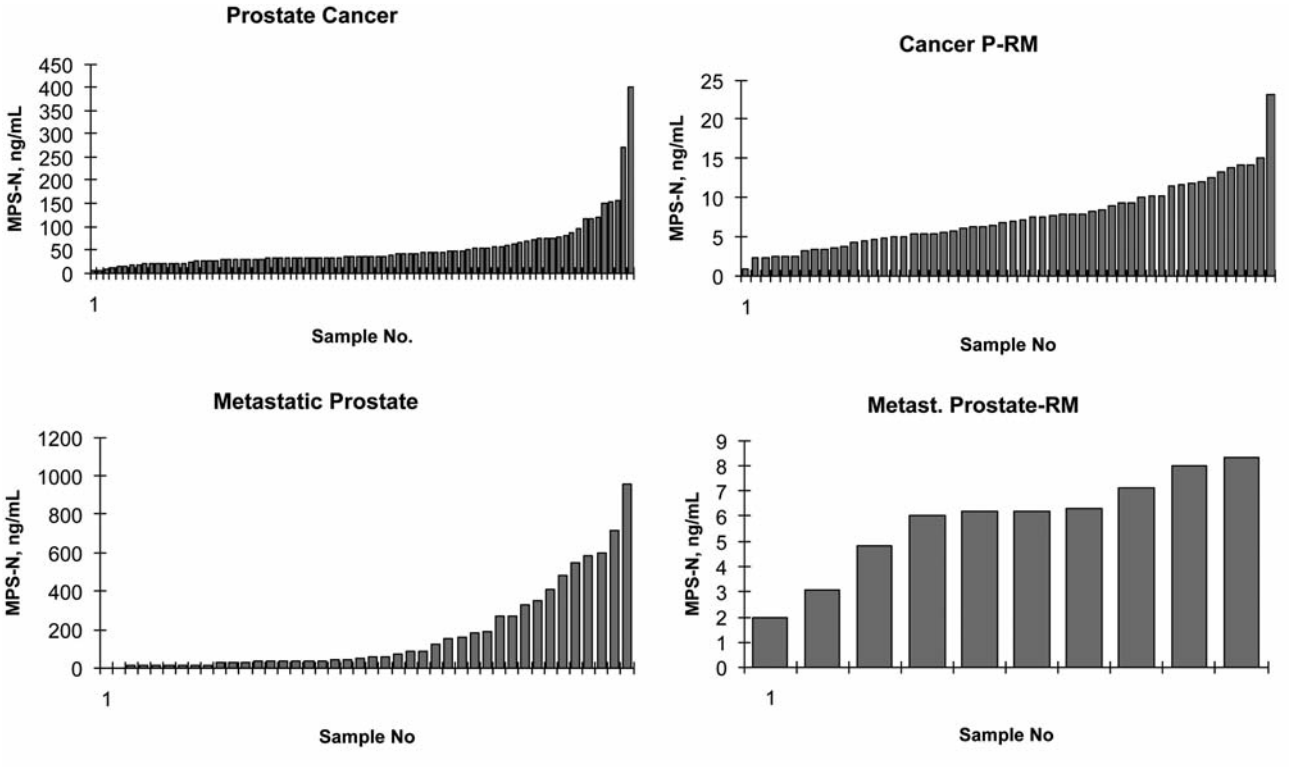
continued

Table V. *continued*

Sample No.	MPS	PSA	Diagnosis	Pathology, stage and conditions
298	85.6	245	Cancer P	PC
455	95.3	353	Cancer P	PC treated 4 y ago
496	117	25	Cancer P	Prostate cancer, possible metastatic, 80 y old
505	117	17.2	Cancer P	Elevated PSA
446	120	4.5	Cancer P	PC treated, radiation therapy 3 y ago
567	151	2	Cancer P	History of prostate cancer
542	154.3	426	Cancer P	72-y-old patient with M1b PC
609	155	1.3	Cancer P	History of prostate cancer; hormonal treatment
61	269.7	98.5	Cancer P	PC poorly diff., status post-radical prostatectomy
600	400	10.6	Cancer P	Stage IV sacral decubitus ulcer; elevated PSA
670	2	18.3	Met. P-RM	PC M1b; hormone treatment: Bone scan: no active metastic disease
513	3.1	15.1	Met. P-RM	PC 2 y ago, treated, remission; M1b
516	4.8	27.5	Met. P-RM	PC consistent with resolving mets; no new lesions
170	6	12.1	Met. P-RM	PC poorly diff., M1b, radiation therapy, Sr-89 therapy, bone healing
512	6.2	145	Met. P-RM	Patient asymptomatic
695	6.2	160	Met. P-RM	Radical prostatectomy 9-y ago; T3aM1b; Hormone/Rad. treatment
18	6.3	852	Met. P-RM	PC poorly diff., TURP, M1b, hormonal therapy, remission
636	7.1	30.7	Met. P-RM	M1b; bone scan shows almost complete resolution of metastatic disease
469	8	1	Met. P-RM	PC T3a/M1b, postive bone scan in L2-3
601	8.3	30.7	Met. P-RM	PC 4-y ago; M1b; Bone scan: complete resolution of mets; no new lesions
507	12	158.5	Metastatic P	PC, L4 metastasis, treated
452	12.5	112	Metastatic P	PC T4a/M1b; Metastasis in sacrum, sclerosis of sacrum metastatis
59	14.2	56.7	Metastatic P	PC, M1b, increased uptake at the right 2nd rib
611	15	145	Metastatic P	M1b PC treated
400	15.2	927	Metastatic P	PC T4N2M1b, treated 1 m ago
265	17.3	65.3	Metastatic P	PC M1b, treated 5 months ago, remission
28	18.2	225	Metastatic P	PC poorly diff., M1b, hormonal therapy
646	19.2	30.7	Metastatic P	M1b; bone scan shows almost complete resolution of metastatic disease
473	20.1	128	Metastatic P	PC poorly diff., T3a/M1b
32	31.89	95.4	Metastatic P	PC poorly diff., M1b, post-radiation therapy for metastatic disease
46	32.5	110	Metastatic P	PC poorly diff., T4a/M1ab
554	32.7	173	Metastatic P	Well diff. CA; T3aM1b; Treated RT; remission
355	35.6	131	Metastatic P	PC poorly diff., T3cN2M1b, hormonal therapy
47	37	337	Metastatic P	PC moderaterly diff., T3c/M1ab
582	37.3	95	Metastatic P	Adeno CA; T4aN2 diagnosed 4-y ago; hormone treatment
578	39.5	1216	Metastatic P	Poorly diff. Adeno CA; T3aM1b; TURP; hormonal therapy
205-R3	40	3356	Metastatic P	PC poorly diff., M1b, treated, strontium therapy for pain, 3rd MPS analysis
558	40	1216	Metastatic P	Poorly diff. Adeno CA; T3aM1b; TURP; hormonal therapy
580	46	158	Metastatic P	Adeno CA; T4N2M1b; Radiotherapy; Bone scan unchanged for 6-month
111	47.3	39	Metastatic P	PC, well diff., M1b, hormonal therapy
9	54.4	99.1	Metastatic P	PC poorly diff., T3c/M1b, untreated
345	58.3	685	Metastatic P	PC, T3M1b, radiostrontium treatment, radiation
97	62.1	20.7	Metastatic P	PC moderately well diff., M1b, untreated
367-R	72	3752	Metastatic P	PC poorly diff., M1b, treated, strontium therapy for pain
647	90.3	135	Metastatic P	PC surgery 3-y ago. M0
359	92.6	186	Metastatic P	PC well diff., T3aN2M1b, diagnosed 1 y ago, hormonal therapy
35	123.3	62.4	Metastatic P	PC poorly diff., M1b
653	158	40	Metastatic P	PC T3M1a
222	162	154	Metastatic P	PC poorly diff., T3a/ N2/M1b, TURP 2 y ago; radiation/strontium therapy
325	186	>1000	Metastatic P	101 y old male, CL leukemia, L femur fracture, PC metastatic/PSA:11281
5	189	91	Metastatic P	PC poorly diff., M1b/NX, TURP, hormonal therapy
514	272	36	Metastatic P	PC post-radiation therapy; stage D2
6	273	377	Metastatic P	PC poorly diff., M1abc, patient died 4 days after sample collection
2	328	3160	Metastatic P	PC poorly diff., M1b, treated strontium therapy for pain
4	351	93.4	Metastatic P	PC poorly diff., T3a, possible M1b
33	407.85	1099	Metastatic P	PC poorly diff., M1abc, radiation , patient died 8 d after sample collection
17	483.6	1734	Metastatic P	PC poorly diff., M1b, N3, chemotherapy, radiation therapy, palliative
398	546.6	1145	Metastatic P	PC T4N2M1b, untreated
185	582	102	Metastatic P	PC poorly diff., T4a/M1b, status post-treatment
583	602.5	2984	Metastatic P	Adeno CA; T4aN2; diagnosed 4-y ago; hormone treatment
364	715	344	Metastatic P	PC, hormonal therapy
210	954	102	Metastatic P	PC poorly diff., N3/M1b/M1c, prostatectomy, radiation/hormone therapy

continued

Table V. *continued*



divide the MPS-1 range of values as follows: <10 ng/mL; 10-20 ng/ mL, and 20 to 30 ng/m. In patients with metastatic cancer of various origins (*e.g.* prostate, lung, melanoma, *etc.*), the MPS-1 levels were in most instances (>70% of the cases) extremely high (100 to 1000 ng/mL). Table II also illustrates patients with prostate cancer stage M1b (metastasis to the bone) that showed the highest levels observed in this study.

Further analysis of the sub-groups with non-malignant diseases revealed that only 1% of the patients with numerous other non-malignant diseases (N=201) had MPS-1 levels > 20 ng/mL. Table II was divided according to type of cancer and analyzed in the following Tables (III to XIV).

Measurement of circulating MPS-1 in serum of patients with non-malignant diseases (Table III). The number of patients studied in this group was 197. The combined results for all non-malignant diseases listed in Table III indicate that 75% of the patients in this group had MPS-1 levels <10 ng/mL. Less than 4% of the patients with these conditions had MPS-1 levels >10-15 ng/mL and, only 12 patients had levels >15-20 ng/ mL.

Measurements of circulating MPS-1 in serum of patients evaluated for benign prostatic hypertrophy (BPH) (Table IV). The number of patients with BPH studied was 48. The BPH untreated patients were plotted at the bottom of Table IV to facilitate comparisons. Individuals with untreated BPH (left chart) and treated BPH (right chart) are shown in graph form at the bottom of Table IV. BPH untreated patients had levels from 2 ng/mL to 50 ng/mL MPS-1. After treatment, 11 patients showed a decrease in MPS-1 from 2 ng/mL to 15 ng/mL. The BPH patients not shown in the graphs were treated by non-surgical means. Thus, MPS-1 is a useful marker to determine removal of BPH tissue from the prostate grand.

Measurements of circulating MPS-1 in serum of patients evaluated for prostate cancer (Table V). A group of 177 patients with prostate cancer were studied. The following groups are shown in graph form at the top or the bottom of Table V: (i) Prostate cancer untreated patients (top left); (ii) prostate cancer treated patients in remission (P-RM) (top right) ; (iii) Untreated metastatic prostate (bottom left); and (iv) treated metastatic prostate cancer in remission (M1b-RM) (bottom right). Note the large decrease in MPS-1 in both prostate cancer and M1b metastatic prostate cancer in P-RM) after treatment of patients. For example, the M1b metastatic prostate cancer in 10 patients showed MPS-1 levels reduced from 2 to 8 ng/mL.

Measurements of circulating MPS-1 in sera of patients evaluated for colorectal cancer (Table VI). The following

Table VI. *Measurement of Circulating MPS in sera of patients evaluated for colorectal cancer.*

Sample No.	MPS/D	PSA	Diagnosis	Pathology, stage and conditions
58	3.3	28.8	Cancer C-RM	Mucinous adeno C of colon, metastatic, PC moderately diff., treated
711	5	ND	Cancer C-RM	Duke's stage III, 1-y ago; chemotherapy; remission
393	5.3	2.2	Cancer C-RM	Colon Adeno-CA, T3N1MX, post-colectomy/chemo 4 m ago, remission
434	6.7	ND	Cancer C-RM	Colon cancer treated 3 y ago. Remission
712	10.8	ND	Cancer C-RM	Duke's C colon CA; chemotherapy; remission
197	12.4	ND	Cancer C-RM	Rectal adeno CA, post-radiation therapy, chemotherapy, Tuberculosis
13.1	17		Cancer C	Colon CA, stage T3N2MX, resected; laryngeal cancer, resected, chemotherapy
396	18.1	27.2	Cancer C	Colon adeno CA, moderately diff.
14.1	21.8		Cancer C	Rectal cancer, resected 2 years ago, radiation therapy, chemotherapy
616	26	44.7	Cancer C	Duke's C colon CA; T4M1b 5-y ago; resection, chemo and rad. therapy
189	30	ND	Cancer C	Well diff. colon adeno CA, resected, L metastasis, stage IV, chemotherapy
8.1	30.4		Cancer C	Status post-right hemicolectomy, chemotherapy, radiation, radiation colitis
284	30.6	ND	Cancer C	Adenocarcinoma of sigmoid colon
9.1	31.2		Cancer C	Colo-rectal, well diff. adeno, resected 50 m ago
624	33.1	17.3	Cancer C	Status post-resection for well-diff. adeno CA of colon
230	38.1	14.5	Cancer C	Duke's B colon CA, elevated PSA
305	38.1	ND	Cancer C	Colon Adeno CA resected 2 y ago; CEA 111; BPH/TURP 2 y ago
714	44.1	ND	Cancer C	History of colon cancer. Elevated CEA
274	47	0.3	Cancer C	PC well diff. T3c, radical prostatectomy, Rad., 2 y; Colon cancer 7 y ago
303	56.7	ND	Cancer C	Sigmoid colon adeno CA; CEA 699
373	68.4	20.3	Cancer C	Colon CA, T3N0M0, post hemicolectomy, 2 y ago; prostatic nodule
588	71.1	22.7	Cancer C	Colon CA; status post-resection 4-y ago. Multiple polyps in colon
380	73.5	ND	Cancer C	Malignant neo rectum, status post -resection, 2 y ago, increased CEA
709	2.4	ND	Met. C-RM	Dukes C; colectomy 7-y ; hepatic lobectomy; 3-y; chemo.; remission
687	2.8	25.4	Met. C-RM	Post-colectomy 1 y ago; Dukes C; well diff. Colon CA; chemotherapy
606	4.6	ND	Met. C-RM	Colon CA, status post -left colectomy 3-y ago; chemotherapy
120	6.5	0.5	Met.. C-RM	Colon carcinoma, multiple lung metastasis, chemotherapy
605	7.2	ND	Met. C-RM	Colon CA; Metastatic; status post-chemotherapy and surgery
700	9	48	Met. C/P-RM	Colon and Prostate CA; surgery 2-y ago; chemotherapy
165	13.1	42.3	Met. C/P-RM	PC, M1b; Colon CA, treated; normal screening examination, remission
668	47.4	ND	Metastatic C	Status post-resection of colo-rectal cancer 3-y ago; liver metastasis
685	50.1	ND	Metastatic C	Well diff. sigmoid colon adeno CA resected 6-m ago; liver metastasis; chemotherapy
7.1	55.1		Metastatic C	Liver metastasis, untreated
470	60.4	6.6	Metastatic C	Metastatic colon cancer to brain, lung and liver
667	65.7	ND	Metastatic C	Adeno CA of Colon, resected 2-y ago; Lung metastasis increasing in size
675	69.6	ND	Metastatic C	Adeno CA of Colon, resected 2-y ago; Lung metastasis increasing in size
607	169.4	ND	Metastatic C	Well diff. adeno CA; status post colectomy and chemotherapy
4.1	253		Metastatic C	Liver metastasis, untreated
708	412	ND	Metastatic C	Adeno CA metastatic to liver; mucin positive; untreated
642	564	5.9	Metastatic C	Well diff. Adeno CA of colon with liver and bone metastasis. Prostate: BPH

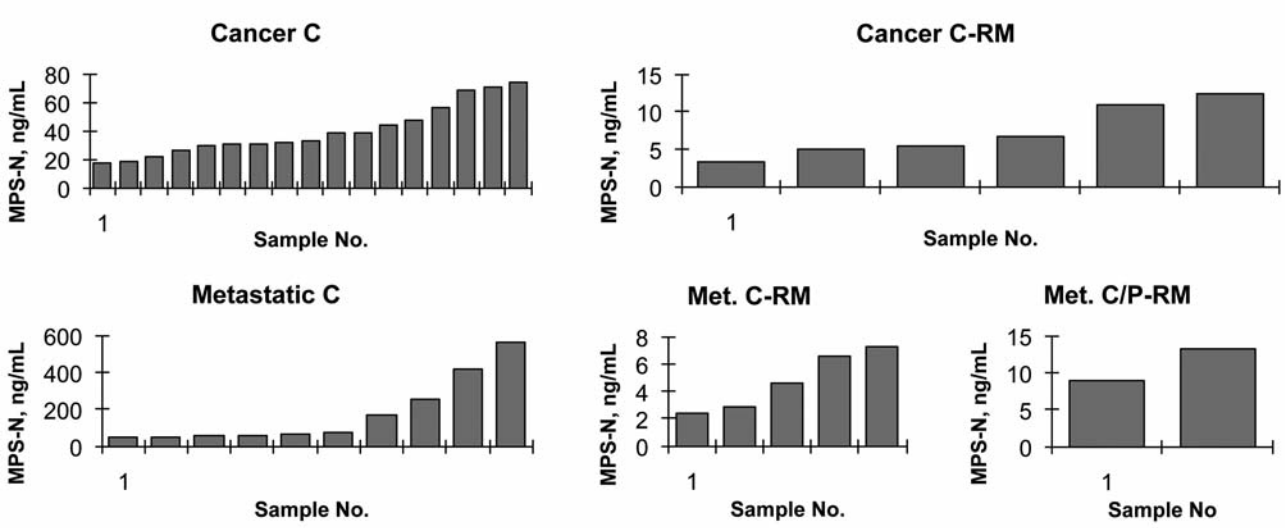


Table VII. *MPS in sera of patients evaluated for hormones*

Tube No.	Assay name	Assay result	Units	MPS results
1	Human Growth Hormone	22.1	ng/ml	7.2
2	Human Growth Hormone	28.2	ng/ml	9
3	Human Growth Hormone	31.2	ng/ml	6.6
4	Human Growth Hormone	46.3	ng/ml	26.4
5	Human Growth Hormone	158	ng/ml	7.5
6	Human Growth Hormone	374	ng/ml	6.9
7	Insulin-like Growth Factor 1	494	ng/ml	8.1
8	Insulin-like Growth Factor 1	571	ng/ml	6.9
9	Insulin-like Growth Factor 1	688	ng/ml	8.1
10	Insulin-like Growth Factor 1	780	ng/ml	19.5
11	Insulin-like Growth Factor 1	826	ng/ml	11.4
12	Insulin-like Growth Factor 1	1058	ng/ml	58.5
13	C-term PTH (Dialysis Pt)	7467	pg/ml	18
14	C- term PTH (Dialysis Pt)	3137	pg/ml	51.3
15	C-term PTH (Dialysis Pt)	7380	pg/ml	9.6
16	C-term PTH (Dialysis Pt)	6661	pg/ml	24
17	C-term PTH (Dialysis Pt)	1551	pg/ml	46.5
18	C-term PTH (Dialysis Pt)	5741	pg/ml	12
19	C-term PTH (Dialysis Pt)	1971	pg/ml	17.7
20	C-term PTH (Dialysis Pt)	4145	pg/ml	11.4
21	C-term PTH (Dialysis Pt)	1953	pg/ml	18.3
22	C-term PTH (Dialysis Pt)	1659	pg/ml	35.4
23	Pt Oleg, PSA after surgery	0.08	ng/ml	11.4
24	Pt Oleg, PSA after surgery	<0.02	ng/ml	7
25	Pt Oleg, PSA after surgery	0.04	ng/ml	8.5
26	Pt Oleg, PSA after surgery	<0.02	ng/ml	5.4
27	Pt Oleg, PSA after surgery	0.03	ng/ml	3.9
28	Pt Oleg, PSA after surgery	0.05	ng/ml	6.9
29	Pt Oleg, PSA after surgery	0.06	ng/ml	6
30	Pt Oleg, PSA after surgery	0.09	ng/ml	3
31	Pt Oleg, PSA after surgery	0.12	ng/ml	8.4
32	Pt Oleg, PSA after surgery	0.14	ng/ml	3.3
33	Pt Vlad, PSA after surgery	0.28	ng/ml	38.7
34	Pt Vlad, PSA after surgery	0.08	ng/ml	12.9
35	Pt Vlad, PSA after surgery	0.02	ng/ml	3.9
36	Pt Vlad, PSA after surgery	<0.02	ng/ml	4.5
37	Pt Vlad, PSA after surgery	0.02	ng/ml	19.2
38	Pt Vlad, PSA after surgery	0.02	ng/ml	6
39	Pt Vlad, PSA after surgery	0.04	ng/ml	8.4
40	Pt Vlad, PSA after surgery	0.02	ng/ml	4.8
41	Pt Vlad, PSA after surgery	0.04	ng/ml	6
42	Pt Vlad, PSA after surgery	0.07	ng/ml	8.7
43	Pt Vlad, PSA after surgery	0.1	ng/ml	7.8
44	Pt Vlad, PSA after surgery	0.11	ng/ml	6.6
45	Pt Dimi, PSA after surgery	0.13	ng/ml	qns
46	Pt Dimi, PSA after surgery	0.02	ng/ml	73.8
47	Pt Dimi, PSA after surgery	<0.02	ng/ml	5.1
48	Pt Dimi, PSA after surgery	<0.02	ng/ml	4.5
49	Pt Dimi, PSA after surgery	0.02	ng/ml	6.6
50	Pt Dimi, PSA after surgery	0.03	ng/ml	3.6
51	Pt Dimi, PSA after surgery	0.02	ng/ml	6
52	Pt Dimi, PSA after surgery	0.03	ng/ml	qns
53	Pt Dimi, PSA after surgery	0.08	ng/ml	6
54	Pt Dimi, PSA after surgery	0.13	ng/ml	14.4
55	Pt Dimi, PSA after surgery	0.15	ng/ml	6.9
56	Pt Dimi, PSA after surgery	0.22	ng/ml	4.5
	AFP: Primary hepatocellular Carcinoma: Monitoring course and therapy.			
57	Alpha Feto Protein	29.3	ng/ml	3.3
61	Alpha Feto Protein	573.4	ng/ml	21.3
60	Alpha Feto Protein	1955.3	ng/ml	35.7
59	Alpha Feto Protein	37.9	ng/ml	46.8
58	Alpha Feto Protein	7991.1	ng/ml	97.2
62	Alpha Feto Protein	1140	ng/ml	111.9
	PSA: Prostatic carcinoma: Monitoring course and therapy.			
63	Prostate Specific Antigen	0.7	ng/ml	2.8
64	Prostate Specific Antigen	1.4	ng/ml	5.1
67	Prostate Specific Antigen	7.7	ng/ml	12
65	Prostate Specific Antigen	3.2	ng/ml	15.6
69	Prostate Specific Antigen	10.9	ng/ml	79.5
66	Prostate Specific Antigen	5	ng/ml	138.9
68	Prostate Specific Antigen	9.9	ng/ml	525
70	Prostate Specific Antigen	98.1	ng/ml	924
	PAP: Prostate cancer			
73	Prostatic Alkaline Phosphatase	3	ng/ml	6.3
76	Prostatic Alkaline Phosphatase	32.5	ng/ml	6.6
71	Prostatic Alkaline Phosphatase	1.5	ng/ml	14.4
74	Prostatic Alkaline Phosphatase	5	ng/ml	33.3
72	Prostatic Alkaline Phosphatase	0.8	ng/ml	35.4
75	Prostatic Alkaline Phosphatase	8.7	ng/ml	139.8
	NSE: Neuroendocrine cell tumors			
77	Neuron Specific Endolase	16.8	ug/ml	13.2
78	Neuron Specific Endolase	9.8	ug/ml	24.6
80	Neuron Specific Endolase	171.6	ug/ml	50.4
81	Neuron Specific Endolase	41.1	ug/ml	399
79	Neuron Specific Endolase	27.2	ug/ml	435
82	Neuron Specific Endolase	629.4	ug/ml	1041
	CA 72-4: Gastric carcinoma			
88	CA 72-4	128.1	U/ml	43.8
87	CA 72-4	7.1	U/ml	55.8
84	CA 72-4	282.9	U/ml	57
86	CA 72-4	75.1	U/ml	106.5
85	CA 72-4	49	U/ml	203.7
83	CA 72-4	18.5	U/ml	330
			AV	132.8
			SD	113.3154711
	CA-15-3: Breast cancer: Monitoring course and therapy.			
92	CA 15-3	107	U/ml	4.2
90	CA 15-3	194	U/ml	7.2
91	CA 15-3	21	U/ml	9.3
93	CA 15-3	79	U/ml	11.4
94	CA 15-3	30	U/ml	27.9
89	CA 15-3	18	U/ml	34.2
95	CA 15-3	29	U/ml	641.7

continued

CA-19-9: Pancreatic carcinoma

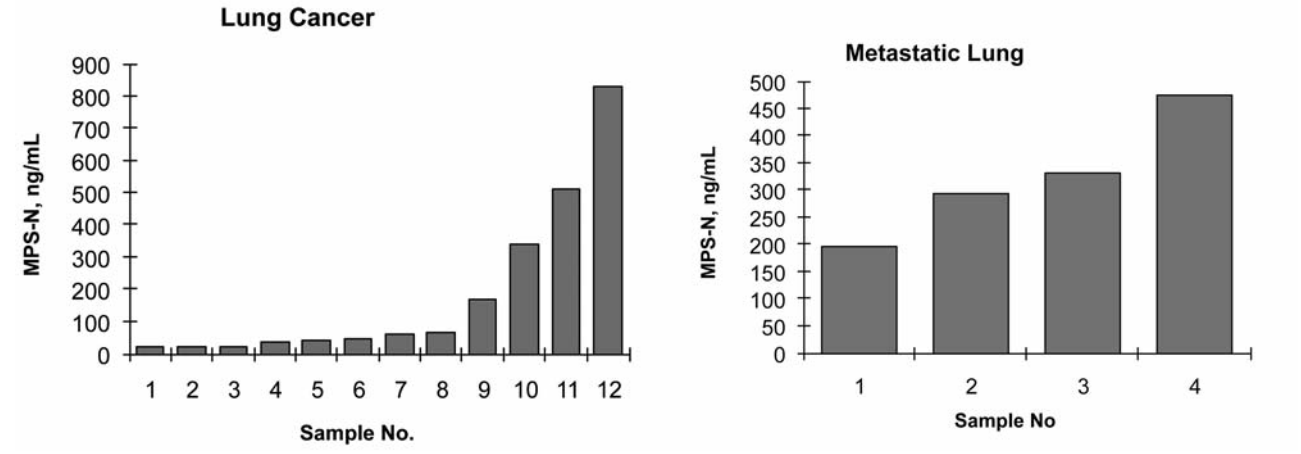
Tube No.	Assay name	Assay result	Units	MPS results
97	CA 19-9	36	U/ml	29.4
100	CA 19-9	263	U/ml	122.1
98	CA 19-9	63	U/ml	237
96	CA 19-9	20	U/ml	260.4
101	CA 19-9	4060	U/ml	288.6
99	CA 19-9	120	U/ml	567
				250.75
				182.9073618
CEA: Monitoring course and therapy of colorectal CA				
107	CEA, ROCHE	2.4	ng/ml	4.2
106	CEA, ROCHE	<0.8	ng/ml	8.2
105	CEA, ABBOTT	1204	ng/ml	18.3
102	CEA, ABBOTT	0.8	ng/ml	27.6
103	CEA, ABBOTT	4.1	ng/ml	44.7
108	CEA, ROCHE	25.3	ng/ml	48.9
109	CEA, ROCHE	1040	ng/ml	272
104	CEA, ABBOTT	46.4	ng/ml	375
CA 125: Montoring course and therapy of ovarian CA				
111	CA 125	5863	U/ml	6
110	CA 125	180	U/ml	13.8
113	CA 125	40	U/ml	72.3
112	CA 125	124	U/ml	73.5
114	CA 125	4413	U/ml	549
115	Normal	19	Female	1.2
118	Normal	22	Female	1.3
117	Normal	21	Female	1.5
120	Normal	24	Female	3
132	Normal	44	Female	3.6
122	Normal	28	Female	3.8
119	Normal	23	Female	4.2
121	Normal	26	Female	4.8
126	Normal	34	Female	5.1
123	Normal	29	Female	5.7
116	Normal	20	Female	6
128	Normal	36	Female	6.3
129	Normal	38	Female	6.3
133	Normal	49	Female	6.6
124	Normal	59	Female	8.1
125	Normal	33	Female	8.1
134	Normal	64	Female	9.3
127	Normal	35	Female	9.9
131	Normal	50	Female	10.8
130	Normal ???	41	Female	27
137	Normal	25	Male	2.1
136	Normal	21	Male	2.4
135	Normal	30	Male	3.9
139	Normal	21	Male	4.2
142	Normal	27	Male	4.5
144	Normal	29	Male	4.5
138	Normal	28	Male	5.4
140	Normal	25	Male	5.4
143	Normal	28	Male	5.7
145	Normal	30	Male	6
147	Normal	33	Male	6.6
150	Normal	36	Male	6.9
141	Normal	26	Male	7.2
151	Normal	39	Male	8.7
152	Normal	41	Male	12
148	Normal	34	Male	19.5
149	Normal	35	Male	21.3
154	Normal	49	Male	21.3
153	Normal ???	45	Male	26.5
146	Normal ???	31	Male	30.6
155	Pregnancy	#87	First	2.3
156	Pregnancy	#87	Second	12
157	Pregnancy	#87	Third	36.7
158	Pregnancy	#1312	First	4.5
159	Pregnancy	#1312	Second	34.8
160	Pregnancy	#1312	Third	30.9
161	Pregnancy	#1053	First	9
162	Pregnancy	#1053	Second	35.9
163	Pregnancy	#1053	Third	51.3
164	Pregnancy	#1503	First	15.6
165	Pregnancy	#1503	Second	30.3
166	Pregnancy	#1503	Third	36.9
167	Pregnancy	#1123	First	7.7
168	Pregnancy	#1123	Second	5.6
169	Pregnancy	#1123	Third	37.3

groups are shown in graph form at the top or bottom of Table VI: (i) Colorectal cancer untreated patients are shown at the top left; (ii) colorectal cancer treated patients in RM (C-RM) are shown at the top right; (iii) untreated metastatic colorectal cancer (C) is shown at the bottom left; (iv) metastatic C-RM (5 patients), and metastatic colon-prostate cancer in RM (2 patients) are shown at the bottom right. The distribution of MPS-1 values for colorectal carcinoma and premalignant polyps are shown in Table VI. Active cancer and cancer in remission are shown for stages T1-T4 and for Metastatic M1a.b.c. Active colon CA showed levels >20 ng/mL which, after treatment and RM, were decreased significantly. The bottom two figures show active C-CA (left) and RM of colon cancer (right).

MPS-1 in serum of patients evaluated for various hormones (Table VII). Human growth hormone showed one out of 6 values for MPS-1 elevated. Insulin-like growth factor 1 showed 2 out of 6 values for MPS-1 elevated. C-term PTH (dialysis patients) showed all MPS-1 values elevated except

Table VIII. *A. Measurement of circulating MPS in sera of patients evaluated for lung cancer.*

Sample No.	MPS/ND	MPS/D	R/D	PSA	Diagnosis	Pathology, stage and conditions
254	2	17.2		16.3	Cancer L	Squamous cell CA of lung
543		18.4		18.3	Cancer L	Adeno CA of Lung resected 6-y ago; recurrence is suspected; BPH
333	0.5	19.5		2.2	Cancer L	Right hiliar mass consistent with cancer
240	1.2	36.4		16	Cancer L	Adenocarcinoma of lung; Benign prostatic hyperplasia of prostate
719		39		11	Cancer L	Prostate CA treated 1-y ago; Lung: Non-small cell CA, unresectable
192	0.3	45	ND		Cancer L	Syndrome of antidiuretic hormone production by lung CA, 2 cm lung mass
412	F:93	56.4		0.2	Cancer L	Right suprahiliar nodule; diabetes
372		62.4		1.7	Cancer L	Adeno-CA of Lung, well diff., T2N0, status post lobectomy, 2 y ago
211	0.2	166.5		1.1	Cancer L	COPD, 84 y old, heavy smoker for 40 y; infiltrate RL, mediastinal mass
341	0.6	337.2		45	Cancer L	Sputum (+) for malignant cells; 10×8 cm RL lobe tumor, pleural effussion
461		508		62	Cancer L	Pleural fluid suspictious for malignant cells, recurrent pleural effussions
411	F:1183	827.3	ND		Cancer L	Lung cancer
382		15.3	ND		Met. L-RM	Non-small cell lung cancer, T3N2M1b, 13 cm mass, radiotherapy 3 m ago
375		194.4		12.6	Metastatic L	Poorly diff. squamous cell CA of lung; brain metastasis, R parietal area
391		291.5		1.7	Metastatic L	Non-small cell CA of lung, M1b
632		331		4.5	Metastatic L	Small cell carcinoma of the lung;liver metastasis
L-1		474.6			Metastatic L	Large mediastinal tumor, adenopathy, multiple liver metastases
275	1.1	34		253	Cancer L-P	Squamous cell CA of lung, well diff., PC well diff., hormone therapy
407		36.3		12.3	Cancer L-P	Non-small cell lung CA 3×5 cm lesion; Bronchial cytology (+); PC treated
537		51.2		42.2	Cancer L-P	Poorly diff. squamous CA of lung; untreated; PC treated 9 m ago
156	2.9	87		88	Metast. L-P	Well diff. CA of prostate; M1b; squamous cell cancer of lung
715		313.6		1999	Metast. L-P	Small cell CA of Lung; M1b; Prostate CA; Ra-chem-therapy; recurrence
727	R-715/3d	499.4		1326	Metast. L-P	Small cell CA of Lung; M1b; Prostate CA; Ra-chem-therapy; recurrence
158	5.7	309		489	Metast. L-P	PC, treated; Small cell CA of lung, treated; M1b
331	1.4	30		1.5	Metastatic L2	Metastatic lung cancer, primary unknown
677	Female	20	ND		Metastatic L2	Metastatic to lung and brain
273	4.5	86.3		32	Metastatic L2	Meningioma 4 years ago; possible metastasis in 5th rib, lung node
365		1073		1.4	Metastatic L2	Large L mass;Thoracentesis: malignant cells mucin (+); adenocarcinoma



continued

one. Low PSA levels corresponded well with low MPS-1 levels except for one patient after surgery (38.7 ng/mL) for MPS-1. Primary hepatocellular carcinoma showed MPS-1 elevated to high levels in 5 out of 6 patients. Prostatic carcinoma showed 10 patients with MPS-1 elevated levels out of 14 separate patients. NSE: Neuroendocrine cell tumors (six patients) all showed very high levels of MPS-1. Gastric carcinoma (CA 72-4) showed all 6 patients with highly elevated MPS-1. Four out of 6 samples of patients with breast cancer (assay CA 15-3) showed 4 samples with

Table VIII. *B. Distribution of MPS values.*

Lung cancer

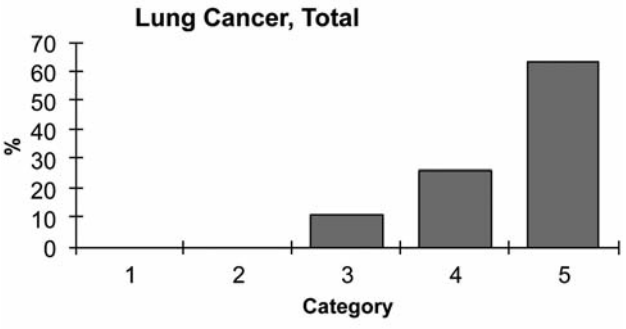
		Percent (ng/mL)				
	Number	<7.0	7.0-10	10.01-20	20.01-50	>50.01
Primary lung	12	0	0	25	25	50
Primary lung, Metastatic	4	0	0	0	0	100
Primary lung and Prostate	3	0	0	0	66.6	33.3
Primary lung/Prostate, M1a,b,c	4	0	0	0	0	100
Secondary, metastatic to lungs	4	0	0	0	50	50
Total	27	0	0	11	26	63

elevated MPS-1. Pancreatic carcinoma (assay CA 19-9) showed that the MPS-1 was greatly elevated in all samples. CEA showed 6 out of 8 samples with greatly elevated MPS-1 levels. Ovarian cancer (assay CA 125) showed 4 out of 5 samples with elevated MPS-1 levels. The values for normal females and males are also shown in this Table. As previously shown, MPS-1 levels are elevated in healthy pregnancy.

Measurement of MPS-1 in serum of patients evaluated for lung cancer (Table VIII-A). The following groups are shown in graph form: (i) lung cancer untreated patients (left) show MPS-1 levels >20 ng/mL in 9 patients and in 3 patients the levels were higher than 10 ng/mL. Thus, all lung cancer patients were positive for MPS-1. Metastatic lung cancer shows very high levels of MPS-1 (from 200 to 450 ng/mL). Table VIII-B shows the distribution of values for lung cancer: (i) Primary lung cancer showed 25 to 50 ng/mL of MPS-1; (ii) primary metastatic lung cancer levels of MPS-1 were 100 ng/mL; (iii) primary lung and prostate cancer in the same patients, showed MPS-1 levels of 66.6 and 33.3 ng/mL; (iv) primary lung and prostate, stage M1,a,b,c levels were >100 ng/mL; and (iv) secondary metastatic to the lungs showed MPS-1 levels of 20.1 to 50 and >50 ng/mL. The graphic distribution of MPS-1 values for lung cancer are shown at the bottom of Table VIII-B and correspond to categories 3, 4, and 5 (10, 20, and >50 ng/mL).

Table IX illustrates measurements of MPS-1 in serum of patients evaluated for head and neck tumors which were then plotted to compare healthy individuals with untreated patients having squamous cell carcinoma (SSC). The MPS-1 values shown in Table IX correspond to untreated patients with SCC. As can be seen the elevated levels of MPS-1 in SCC are useful to detect SCC patients, confirming previous results (18-19).

Table X shows the levels of MPS-1 and CA-15-3 in the same serum specimens of breast cancer patients in different



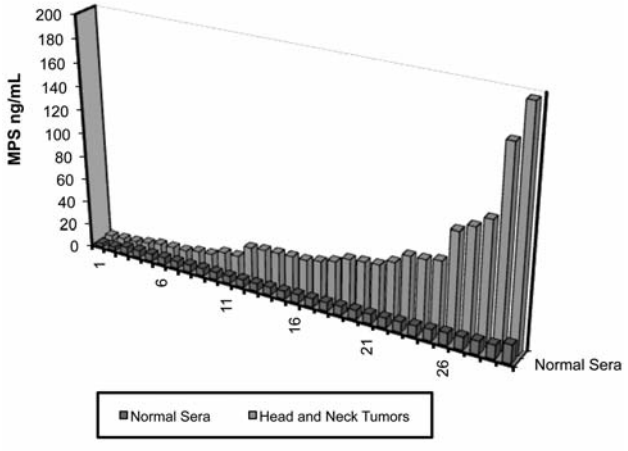
clinical stages, and correlate these serum values with cancer stages. The levels of both MPS-1 and CA-15-3 were plotted to investigate the correlation of cancer stages with tumor marker levels.

The plotting of MPS-1 values in untreated breast cancer patients corresponding to Table X, which are organized in ascending MPS-1 concentrations, show the striking importance of the MPS-1 test for early detection of breast cancer and its correlation with clinical stages. The individual values plotted for each marker correspond to tumor marker measurements done in the same samples. In the plotting, the vertical lines separate from left to right breast cancer stages 0, I, II, III, and IV. Stage 0 (T_0) indicates non-invasive carcinoma *in situ* and Paget's disease of the nipple. Stage (I_1), tumors of <2 cm. Stage II (T_2) tumors from >2 cm to <5 cm. Stage III (T_3), tumor of >5 cm. Stage IV (M), distant metastasis present.

The breast cancer tumor marker/stage plotting, obtained from Table X, shows a study which includes 200 patients ranging from T_0 to Stage IV (M). The comparison of MPS-1 with the routine tumor markers CA 15-3 and CEA are also shown. CA-15-3 and CEA values were of little or no clinical use to correlate with breast cancer stages. It is undeniable that the use of MPS-1, is far superior for the detection of

Table IX. *Head and neck tumors.*

ID	Normal sera	Head and neck tumors
1	3.1	4.7
2	3.1	5.2
3	6	5.7
4	6.1	7.5
5	6.2	9.5
6	6.2	9.9
7	6.2	10.1
8	6.3	12.5
9	6.4	13.5
10	6.4	18.1
11	6.4	18.3
12	6.5	28.8
13	6.5	30.1
14	6.8	30.7
15	6.9	31.1
16	7.3	31.2
17	7.4	33.4
18	7.5	36.7
19	7.7	41.9
20	8.1	43.1
21	8.2	44
22	8.5	49.4
23	8.9	57.9
24	9.3	58.5
25	9.9	60.7
26	10.8	87.7
27	11	94.1
28	11.4	103
29	11.9	165
30	15.9	197



early breast cancer than CA-15-3 or CEA, which were ineffective.

Table XI shows 30 separate healthy female serum specimens, in which the MPS-1 was measured. As can be noted, from 29 normal samples 28 were in the normal range of about 10 ng/mL, while only one sample (No. 13) showed levels of 15 ng/mL indicating that it was in the gray zone of the MPS-1 test, and thus indicated that the assay should be repeated in 3 months. Overall 99% ±2 SD of the MPS-1 values were either about 10 ng/mL ±2 SD or were below that level. Thus, the MPS-1 test is highly reliable in determining the individuals who are highly unlikely to develop a carcinogenic process. The bar graph shows the healthy female MPS-1 serum levels for comparison (values obtained from Table IX). Table XII was used to generate the graphs. Table XII (breast normal values), consisting of 120 patient samples is shown for comparison. The plotting of the 120 samples of MPS-1, CA 15-3 and CEA is also shown (Table XII). The markers are also shown in 120 separate determinations at the bottom of Table XII-breast normal values for MPS-1, CA 15-3 and CEA, indicating further the validity of the MPS-1 serum test for the detection of breast cancer.

Table XIII compares early breast cancer stages 0, I and II with normal female serum from healthy individuals. The age, stage, CEA, CA 15-3 and two separate measurements of MPS-1, E1 and E2, in two separate MPS-1 assays are shown to determine the inter-assay coefficient of variation (14). The findings indicate that stages 0, I and II can be detected early by the MPS-1 test in >90% of the cases, confirming previous results presented above.

Table XIV shows comprehensive and detailed data on a large number of patients with advanced breast cancer (stages III and IV). A few early cancers are also included in this series (stages I and II). Table XIX shows stage I (8 patients), stage II (5 patients), stage III (9 patients), stage III/IV (5 patients), and stage IV (13 patients). Table XIV indicates the response to various types of therapy and status as: (i) stable; (ii) progression; and (iii) response to therapy. The MPS-1 protein was highly increased in all patients in advanced stages, irrespective of response to therapy, except in four patients.

Discussion

MPS-1 as a "universal or broad spectrum tumor marker is defined as an antigen found in abnormal concentrations in the blood of a large number of patients (>90%) suffering from various forms of benign and malignant neoplastic processes (20-23). The results presented in this article demonstrate that the MPS-1 antigen is a ubiquitous tumor marker that may be useful in early detection, prognosis and management of various types of benign and malignant tumors.

The syncytiotrophoblasts are multinucleated cells present in the placenta of embryos (Figure 2A). The outer syncytial layer of the trophoblasts actively invades the uterine wall. It forms the outer fetal component of the placenta and massively increases the surface area available for nutrient exchange between the mother and the fetus. The syncytiotrophoblast cells secrete human chorionic gonadotropin (hCG). Figure 2C

Table X. *Comparison of MPS-1 with the routine tumor markers CA 15-3, CEA and breast cancer stage.*

#	Stage	MPS-1	CA 15-3	CEA
13	0	4.7	18.5	1.3
8	0	22.6	32	1.2
15	0	37.4	21	4.8
20	0	38	40.6	2.6
10	0	40.5	14.6	2.3
7	0	47	15	0.3
18	0	54	16.1	5.9
5	0	59	22	3.1
3	0	62.4	23	2.3
6	0	72.5	12.1	24.4
2	0	75.6	25	1.8
16	0	110	24.8	1.5
14	0	126	14	0.1
9	0	162	29.7	4.9
4	0	207	21	0.8
17	0	235	20.6	1.9
19	0	241	16.9	2.3
35	I	4.5	22.4	0.5
43	I	7.3	23	0.7
27	I	8.5	12	0.4
35	I	8.6	11	18.7
50	I	9.9	18.3	3.2
48	I	12.6	24	0.5
34	I	13	12.2	11.5
37	I	13.4	35.4	25.4
42	I	14	15.4	4.3
6	I	14.2	16.1	1.1
30	I	14.9	16	4.4
33	I	16.5	7	0.2
47	I	16.7	7	0.6
7	I	18.1	19.9	2.4
23	I	22.6	41.8	1.7
5A	I	24.4	26	1.2
46	I	25.1	21	0.5
32	I	25.3	9	1
32	I	25.7	14.9	17.2
48	I	25.8	21.6	0.5
38	I	28.6	27.2	0.9
49	I	30.2	20.7	0.7
39	I	30.7	31.3	25.4
29	I	31	17.2	1.2
46	I	36.8	23.7	0.9
40	I	38.5	21.8	0.5
5B	I	42.2	27	1.4
31	I	42.5	15.6	29.1
36	I	43.1	23.6	0.5
45	I	45.7	17.1	4.5
34	I	53.9	25	0.9
41	I	54.3	33.5	3
72	I	59.5	41	12.9
2A	I	60.2	12	5.1
47	I	60.7	19.2	3.2
28	I	61.9	22.7	1
44	I	66.5	18.4	3.2
75	I	69.2	73	30.6
25	I	71.4	18	3
34	I	74.2	49	0.6
24	I	74.6	30	1.4
2B	I	76.6	39	10.9
73	I	90.5	61	16.1
26	I	96	15	1.5
5C	I	100	24	1.2
22	I	107	20	1.5
33	I	123	11.1	10.9
71	I	133	16	6.4
31	I	137	12	0.9
2C	I	155	16	6.4
18	I	188	19.2	0.4
21	I	245	14	0.4
17	I	481	13.8	2.2
35	II	5.3	17	0.2
80	II	6.5	15.7	5.4
53	II	14.5	35	2.2
70	II	14.6	35.7	1.1
69	II	15	31.9	1.1
75	II	16.4	41.3	2.4
66	II	18.2	24.1	6.4
76	II	20.2	37.9	2.1
67	II	20.6	74.8	3
68	II	20.8	15.5	5.4
73	II	24.4	13.2	2.2
47	II	24.5	9	3.4
54	II	24.8	29	1.9
63	II	24.9	11.1	5.4
59	II	25	10	0.7
78	II	26.8	60.4	10.1
79	II	27	45.5	2.9
94	II	27.9	30	6
28	II	30.1	21.9	4.2
65	II	31.1	23.7	25.4
9A	II	31.8	30	5.3
53	II	34.1	8.7	0.9
89	II	34.2	18	5
36	II	36.2	15	1.7
49	II	36.9	14	2.6
48	II	37.8	13	13
74	II	38.4	10.9	5.4
57	II	39.6	21	15.4
37	II	39.8	13	0.7
62	II	43.5	9.9	1.6
52	II	43.7	12	1.7
41	II	44.1	23.7	1.3
77	II	48.9	50.5	2.8
71	II	50.1	53	2.4
72	II	51.4	63.2	3.2
54	II	52	24	3.3
42	II	53.1	16	3
45	II	54.1	16	3
60	II	61	20	1.6
58	II	62.9	22	2.3
56	II	63.6	35	0
32	II	65.9	17	0.3
51	II	67	25.3	2.3
52	II	67.6	40	2.3
64	II	70.5	48.3	2.1
21	II	73.7	11	0.8

continued

Table X. *continued*.

#	Stage	MPS-1	CA 15-3	CEA
39	II	83.6	14	1.8
55	II	92.3	23	1.7
33	II	104	15	3.9
9B	II	113	30	9
43	II	133	14.1	2.2
55	II	137	24	9
40	II	138	24	2.9
19	II	144	16	0.8
56	II	156	20	2
22	II	163	18	2.2
24	II	171	13	0.4
31	II	202	22	2.8
1	II	205	51	1.4
1	II	205	32.5	0.2
15	II	226	38	0.5
46	II	229	10	0.5
25	II	231	11	0
20	II	245	24.8	3.6
44	II	275	12	2
30	II	281	20	0.5
61	II	308	25	4.6
29	II	342	19	2.2
26	II	347	11	0
23	II	383	15	0.4
38	II	423	30	4.9
27	II	475	83	2.3
13	III	12.4	16.4	0.8
1B	III	16.8	170	39.3
10	III	21.4	17.6	1.9
50	III	27.6	49	0
40	III	31.2	56	7.6
49	III	34	39	0
51	III	35.1	66	14.9
39	III	41.1	51	9.6
38	III	44.3	76	9
65	III	50.8	280	9.5
1A	III	51.1	124	11.6
67	III	56.1	84	11.6
9	III	58.6	16.9	1.2
74	III	58.7	132	33
3	III	99.9	18	1.7
66	III	101	66	10.3
10C	III	120	57	4.9
10A	III	129	107	5
10B	III	140	50	0
8	III	171	9.7	0
14	III	175	16.3	1.5
12	III	226	20.2	1.5
4	III	227	18.5	1.2
70	III	332	86	6
7B	IV	18.5	28	32
2	IV	19.1	47.1	25.8
11	IV	23.4	8.4	3.8
41	IV	27.8	43	2.6
4B	IV	29.1	87	14.6
4A	IV	30.8	80	126.6
5	IV	36.7	10.9	4.8
6C	IV	39.1	80	10
42	IV	39.3	68	2.5
57	IV	44.6	37	0
37	IV	58.3	143	12.4
44	IV	58.6	18	2.8
43	IV	65.6	68	2.5
16	IV	69.2	18.8	6.2
58	IV	74.4	32	0
8A	IV	74.5	25	1.4
45	IV	75.6	46	2.4
60	IV	76	18	5.6
59	IV	81.1	37	0
7C	IV	83.4	80	9.5
36	IV	99.8	162	9.3
3B	IV	108	60	12.6
6A	IV	115	28	16.6
3A	IV	119.1	50	12
12	IV	142	586	11.4
11	IV	145	519	2.3
62	IV	175	13	5.3
8B	IV	176	32	8.1
6B	IV	206	87	3.1
68	IV	210	176	7.5
69	IV	227	129	6.8
3C	IV	258	80	14.5
8C	IV	268	54	5.9
64	IV	307	13	3.6
95	IV	320	29	6
61	IV	334	16	6
63	IV	365	18	5

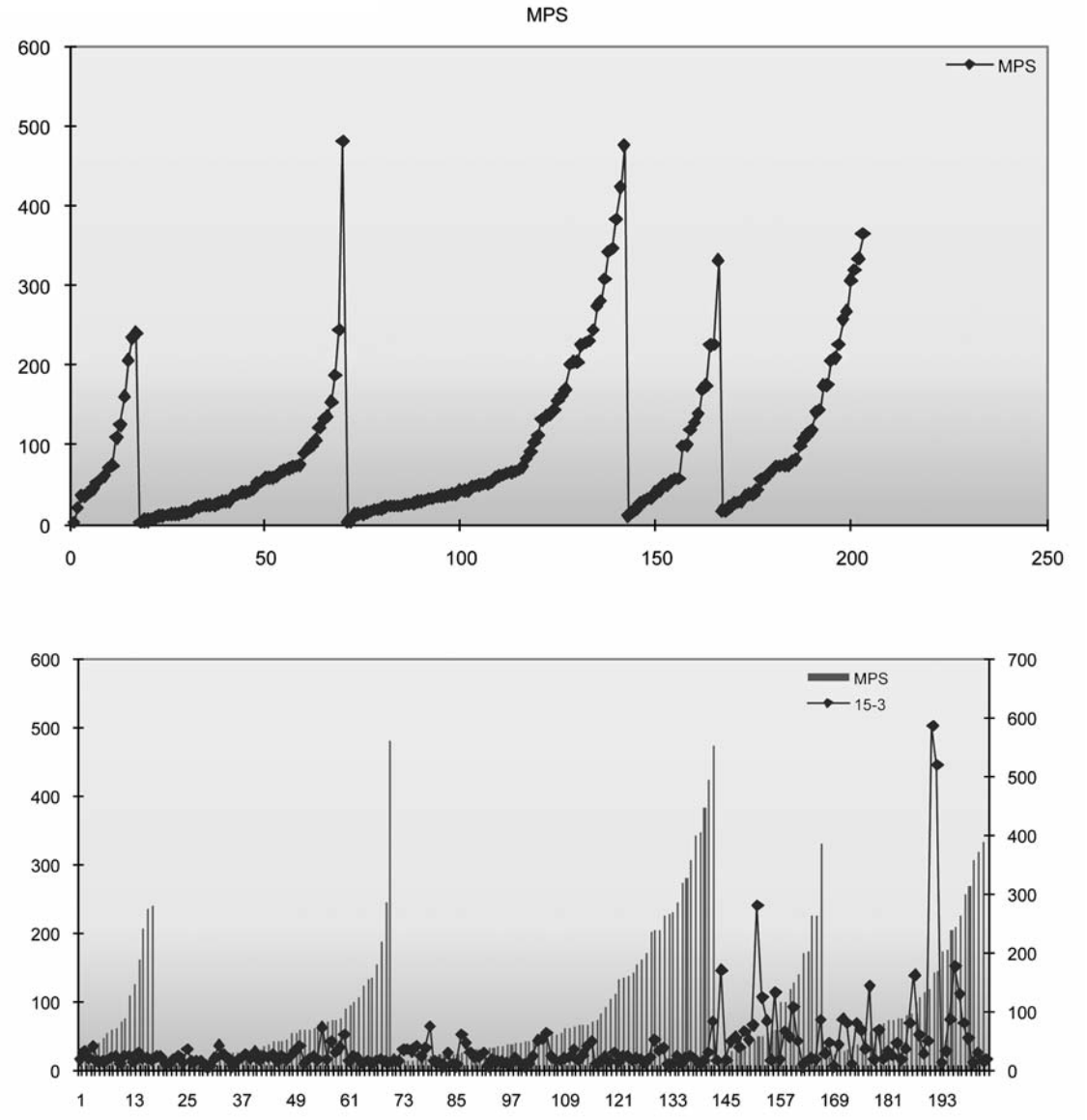
continued

(bottom) shows that the pregnant women studied secrete MPS-1 into the blood during the first, second and third trimester of pregnancy and the levels progressively increase in a time dependent fashion. Figure 2A shows the syncytiotrophoblasts from which the MPS-1 is released into the mother's circulation. These results suggest that MPS-1 may have a role in invasion of normal tissues in oncogenic processes.

A preliminary attempt determined the ratio of MPS-1 to apoptosis to be greater in melanoma than in basal cell carcinoma and benign nevus (Figure 5) (23). Interestingly, the distribution is different. While in melanoma MPS-1 was easily detected in serum, the benign nevi showed no traces of MPS-1.

It can be suggested that the rapid growth of melanomas in a disorderly fashion and its high phagocytic capacity are reflected by the *MPS-1/apoptosis ratios*, in which a large proportion of MPS-1 is released in the circulation by apoptosis and phagocytosis by melanoma cells of surrounding keratinocytes (Figure 4A, B and C). In contrast, the MPS-1 staining pattern of *benign nevi* is in an orderly gradient as

Table X. *continued*.



clearly shown in Figure 5 A, B and C. The corresponding apoptosis staining pattern in the same benign nevi is also present in a gradient but in a vectorial opposite direction to the MPS-1 gradient, as also shown in Figure 5 A, B and C, making it not possible for MPS-1 to be released into the circulation. Three dimensional tomographic reconstruction of tissue slices corresponding to *benign nevi* tissues (Figure 5 A, B and C), alternatively stained for MPS-1 and apoptosis shows an orderly pattern (Figure 5C).

Breast cancer is an increasing medical problem, as demonstrated by its high incidence in numerous countries around the world (24-26). In the USA, breast cancer is the most common female neoplasm and the second most common cause of cancer death. Breast cancer research has focused on methods to detect breast cancer at its earlier stages, to cure the disease after early diagnosis. At present, imaging techniques that exploit the different physical properties of the cancer and normal or non-malignant surrounding tissues are used in the early detection of breast cancer. Imaging is also being used as a guide for biopsy. However, the majority of women in the USA (80%), who undergo breast biopsies do not have cancer, indicating the imprecision of imaging techniques (25).

Recognition of the limitations of the latest imaging technologies for early diagnosis of breast cancer and screening of breast cancer has led to the evaluation of new

Table XI. *Normal female MPS serum levels.*

Sample	MPS	Diagnosis	DOD	Days	Age
1	8.2	Norm F S	3/3/96	0	31
2	6.9	NFS	22/3/96	19	31
3	6.5	NFS	29/3/96	26	31
4	6.3	NFS	1/3/96	0	26
5	11.4	NFS	14/3/96	13	26
6	11.9	NFS	29/3/96	28	26
7	11	NFS	9/3/96	0	25
8	6.4	NFS	14/3/96	5	25
9	6.2	NFS	3/4/96	25	25
10	8.9	NFS	14/3/96	0	29
11	6.4	NFS	25/3/96	11	29
12	7.3	NFS	4/4/96	21	29
13	15.9	NFS	15/3/96	0	30
14	10.8	NFS	29/3/96	14	30
15	9.3	NFS	3/4/96	19	30
16	6.1	NFS	10/3/96	0	29
17	7.7	NFS	26/3/96	16	29
18	3.1	NFS	29/3/96	19	29
19	3.1	NFS	3/5/96	0	26
20	6	NFS	18/5/96	15	26
21	6.8	NFS	29/5/96	26	26
22	8.1	NFS	19/4/96	0	26
23	7.5	NFS	27/4/96	12	26
24	6.2	NFS	10/5/96	21	26
25	9.9	NFS	10/3/96	0	31
26	6.4	NFS	26/3/96	16	31
27	6.5	NFS	14/4/96	35	31
28	6.2	NFS	10/5/96	0	38
29	7.4	NFS	15/5/96	5	38
30	8.5	NFS	1/6/96	22	38

methods of early cancer detection by measuring serum biochemical markers (antigens) released into the blood. More recently the use of proteomic analysis provides unique information which can identify various forms of the same marker (*e.g.*, MPS-1, MPS-like proteins, MPS-1 covalently bound to serum carrier proteins (US Pat. No. 5,955,387) which may be also useful for early detection of breast cancer (7, 11, 13, 24-27). Because of the high incidence of breast cancer even small improvements in early detection and treatment may represent a large number of lives saved or prolonged.

The experimental tumor marker MPS-1 evolved from cloning of MPS-1 from breast cancer cells and the study of ribosomal proteins (1-9). Since MPS-1 protein is produced by many different types of cancer it is not possible to determine the site of origin or tumor type. However, the presence of elevated levels of MPS-1 clearly indicates that in an otherwise healthy individual carcinogenesis is most likely evolving. Thus, the combination of detection of MPS-1 (AA 2-17 peptide) antigen in the serum at elevated levels follow by diagnostic imaging techniques may provide an economic way of early detection of breast cancer.

Conclusion

The MPS-1 test, which measures a unique serum antigen common to a variety of oncogenic processes, provides the following clinically useful information: (i) First and foremost the MPS-1 test narrows down the uncertainty zone concerning the presence or absence of an oncogenic process; (ii) the MPS-1 test may be useful to signal cases where further clinical investigation of oncogenic processes by a physician is needed; and, (iii) the MPS-1 test is an indicator of potential clinical problems in the area of oncogenesis.

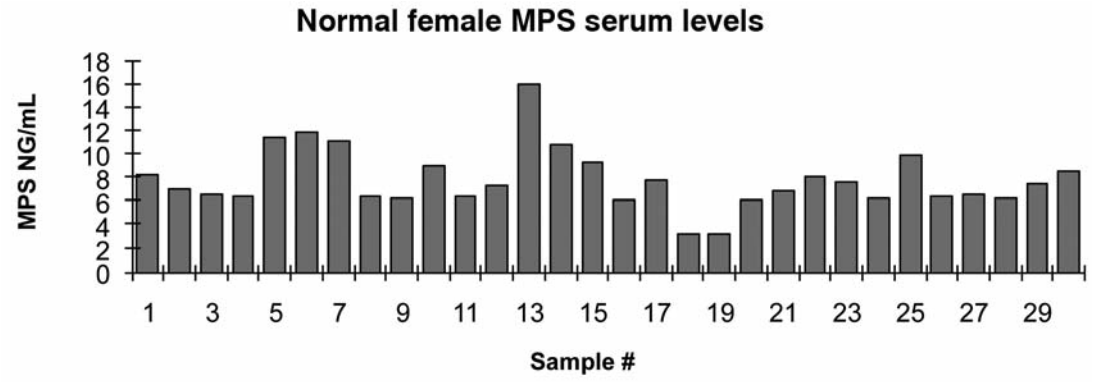
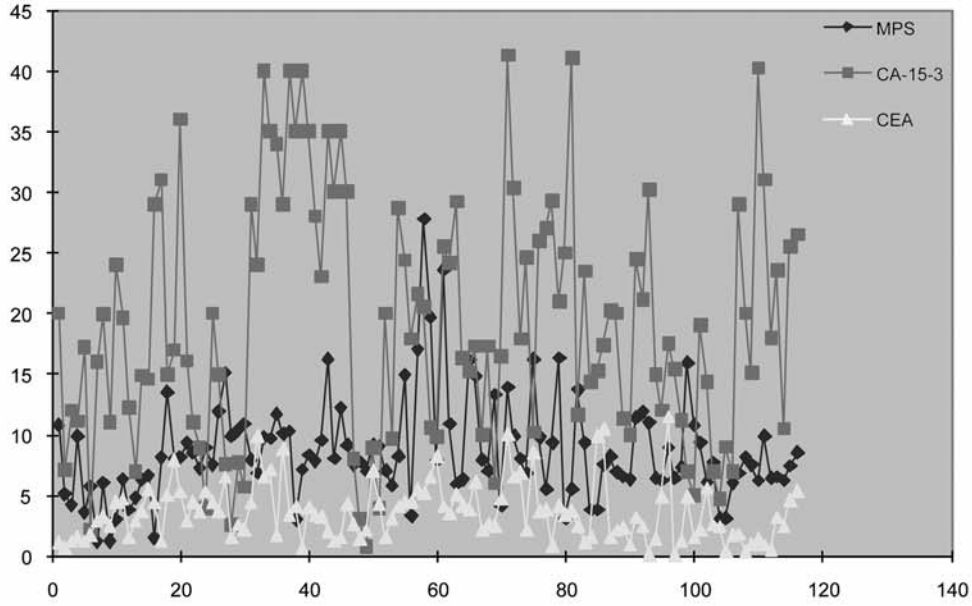


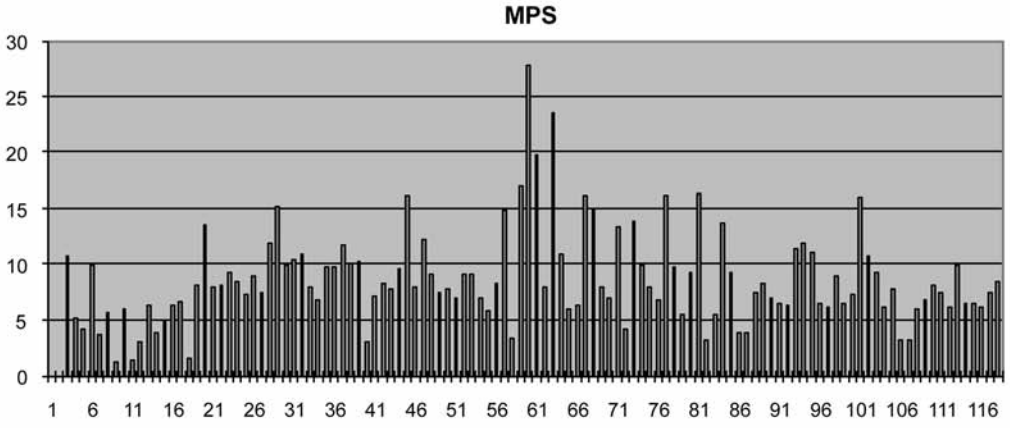
Table XII. *Breast normal values*.

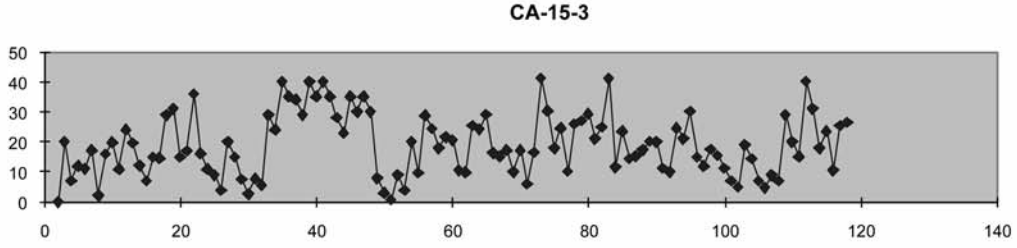
Normal values						Normal values					
Tube #	Patient	Age	MPS	CA-15-3	CEA	Tube #	Patient	Age	MPS	CA-15-3	CEA
131	Normal	50	10.8	20	1.1	89	Normal	29	19.7	10.6	6.5
126	Normal	34	5.1	7.1	0.7	90	Normal	20	7.9	9.8	8.2
119	Normal	23	4.2	12	1.2	91	Normal	20	23.6	25.5	4.1
127	Normal	35	9.9	11.1	1.6	92	Normal	25	10.9	24.2	3.5
132	Normal	44	3.6	17.2	1.2	93	Normal	39	5.9	29.2	5.1
123	Normal	29	5.7	2.1	1.7	95	Normal	53	6.3	16.3	4.2
115	Normal	19	1.2	16	2.9	96	Normal	34	16.1	15.2	3.9
116	Normal	20	6	19.9	3.3	97	Normal	27	14.8	17.3	6.1
118	Normal	22	1.3	11	2.5	98	Normal	39	7.9	10	2.1
120	Normal	24	3	24	4.5	99	Normal	33	7	17.3	2.7
129	Normal	38	6.3	19.6	4.7	101	Normal	22	13.3	6	2.5
122	Normal	28	3.8	12.2	1.5	103	Normal	31	4.1	16.5	4.7
121	Normal	26	4.8	7	2.9	104	Normal	47	13.9	41.3	10
128	Normal	36	6.3	14.9	3.7	105	Normal	51	9.9	30.3	6.5
133	Normal	49	6.6	14.6	5.5	106	Normal	47	8	17.9	6.9
117	Normal	21	1.5	29	4.4	107	Normal	19	6.8	24.6	2.1
125	Normal	33	8.1	31	1.2	108	Normal	43	16.2	10.2	8.5
130	Normal	41	13.5	15	5	109	Normal	37	9.8	26	3.7
140	Normal	50	8	17	7.9	110	Normal	27	5.5	27	3.9
124	Normal	59	8.1	36	5.3	111	Normal	32	9.3	29.3	0.8
134	Normal	64	9.3	16.1	2.9	112	Normal	42	16.3	21	4.2
1	Normal	31	8.5	11	4.5	113	Normal	21	3.1	25	3.4
2	Normal	31	7.2	9	3.7	114	Normal	27	5.5	41	3.7
3	Normal	31	8.9	4	5.3	115	Normal	30	13.7	11.6	2.5
4	Normal	26	7.5	20	4.5	116	Normal	31	9.3	23.5	1.1
5	Normal	26	11.9	15	3.7	117	Normal	34	3.8	14.4	1.6
6	Normal	26	15.1	8	6.5	118	Normal	53	3.8	15.3	9.9
7	Normal	25	9.9	3	1.5	119	Normal	52	7.5	17.4	10.5
8	Normal	25	10.4	8	2.6	1	Normal	31	8.2	20.2	1.5
9	Normal	25	10.9	6	2.2	2	Normal	30	6.9	20	2.1
10	Normal	29	7.9	29	4.4	3	Normal	29	6.5	11.3	2.3
11	Normal	29	6.8	24	9.9	4	Normal	26	6.3	10	0.9
12	Normal	29	9.8	40	6.5	5	Normal	27	11.4	24.5	3.2
13	Normal	30	9.7	35	7.1	6	Normal	25	11.9	21.1	2.4
14	Normal	30	11.7	34	1.7	7	Normal	25	11	30.2	0.2
15	Normal	30	10.1	29	8.8	8	Normal	26	6.4	15	1.4
16	Normal	29	10.3	40	3.4	9	Normal	24	6.2	12	4.9
17	Normal	29	3	35	4.1	10	Normal	29	8.9	17.5	11.5
18	Normal	29	7.1	40	0.7	11	Normal	28	6.4	15.4	0.1
19	Normal	26	8.3	35	4	12	Normal	30	7.3	11	1.3
20	Normal	26	7.8	28	3.4	13	Normal	30	15.9	7	4.9
21	Normal	26	9.5	23	3.3	14	Normal	31	10.8	5	1.5
22	Normal	26	16.2	35	2	15	Normal	29	9.3	19	2.2
23	Normal	26	8	30	1.2	16	Normal	29	6.1	14	5.6
24	Normal	26	12.2	35	1.5	17	Normal	30	7.7	7	2.6
25	Normal	31	9.1	30	4.3	18	Normal	26	3.1	5	2.4
26	Normal	31	7.5	8	2.7	19	Normal	29	3.1	9	0.4
27	Normal	31	7.7	3	1.4	20	Normal	30	6	7	1.7
28	Normal	38	7	1	2.1	21	Normal	26	6.8	29	1.8
29	Normal	38	9.1	9	7	22	Normal	27	8.1	20	0.4
30	Normal	38	9	4	4.3	23	Normal	31	7.5	15.1	1
31	Normal	34	7	20	1.5	24	Normal	33	6.2	40.2	1.4
81	Normal	29	5.8	9.7	3.1	25	Normal	38	9.9	31	0.9
82	Normal	39	8.2	28.7	4.1	26	Normal	39	6.4	18	0.5
84	Normal	19	14.9	24.4	4.5	27	Normal	26	6.5	23.6	3.2
86	Normal	19	3.3	17.9	4.5	28	Normal	30	6.2	10.5	2.4
87	Normal	22	17	21.6	5.5	29	Normal	31	7.4	25.5	4.6
88	Normal	47	27.8	20.5	5.2	30	Normal	29	8.5	26.5	5.4

continued

Table XII. *continued*







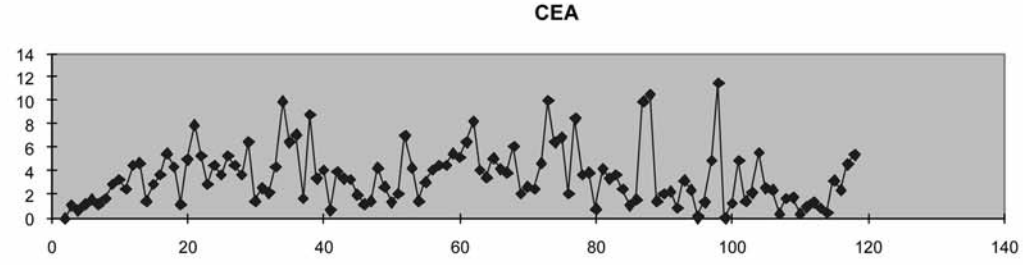


Table XIII. *Breast cancer MPS levels*.

#	Age	Gender	Site	Stage	CEA	CA 15-3	MPS E1	MPS E2
1	59	F	Breast	0	1.4	51	205	92/156
2	84	F	Breast	0	1.8	25	75.6	90.7
3	71	F	Breast	0	2.3	23	62.4	66
4	80	F	Breast	0	0.8	21	207	157
5	66	F	Breast	0	3.1	22	76.9	59
6	58	F	Breast	0	24.4	12.1	107	72.5
7	48	F	Breast	0	0.3	15	96.8	47
8	57	F	Breast	0	1.2	32	37.2	22.6
9	64	F	Breast	0	4.9	29.7	162	213
10	64	F	Breast	0	2.3	14.6	99.2	40.5
11	64	F	Breast	0	2.3	726	145	129
12	43	F	Breast	0	11.4	1066	142	120
13	41	F	Breast	0	1.3	185	4.7	7.1
14	77	F	Breast	0	0.1	14	126	121
15	51	F	Breast	0	4.8	21	37.4	16.3
16	70	F	Breast	0	1.5	24.8	110	128
17	70	F	Breast	0	1.9	20.6	235	219
18	59	F	Breast	0	5.9	16.1	102	54
19	82	F	Breast	0	2.3	16.9	316	241
20	58	F	Breast	0	2.6	40.6	38	31.1
21	55	F	Breast	I	0.4	14	245	258
22	75	F	Breast	I	1.5	20	107	89.3
23	68	F	Breast	I	1.7	41.8	22.6	34.8
24	80	F	Breast	I	1.4	30	74.6	47.3
25	66	F	Breast	I	3	18	71.4	33.7
26	63	F	Breast	I	1.5	15	502	96.6
27	73	F	Breast	I	0.4	12	8.5	16
28	74	F	Breast	I	1	22.7	61.9	82.9
29	65	F	Breast	I	1.2	17.2	130	31
30	79	F	Breast	I	4.4	16	14.9	12.8
31	66	F	Breast	I	0.9	12	137	116
32	71	F	Breast	I	1	9	25.3	20.4
33	68	F	Breast	I	0.2	7	16.5	14.1
34	52	F	Breast	I	0.9	25	53.9	75.1
35	unk	F	Breast	I	0.5	22.4	4.5	5.1
36	unk	F	Breast	I	0.5	23.6	43.1	40
37	unk	F	Breast	I	25.4	35.4	13.4	10.9
38	83	F	Breast	I	0.9	27.2	48.6	28.6
39	58	F	Breast	I	25.4	31.3	30.7	36
40	70	F	Breast	I	0.5	21.8	38.5	13.6
41	76	F	Breast	I	3	33.5	54.3	39.8
42	80	F	Breast	I	4.3	15.4	7.5	13.9
43	82	F	Breast	I	0.7	23	7.3	8.9
44	59	F	Breast	I	3.2	18.4	66.5	85.3
45	57	F	Breast	I	4.5	17.1	45.7	30.1
46	83	F	Breast	I	0.9	23.7	36.8	45.3
47	59	F	Breast	I	3.2	19.2	60.7	63.2
48	72	F	Breast	I	0.5	21.6	25.8	16.8
49	42	F	Breast	I	0.7	20.7	30.2	46.8
50	61	F	Breast	I	3.2	18.3	9.9	11.4
51	unk	F	Breast	II	2.3	25.3	67	39.6
52	80	F	Breast	II	1.7	12	43.7	101
53	50	F	Breast	II	0.9	8.7	34.1	26.1
54	71	F	Breast	II	3.3	24	52	50.9
55	87	F	Breast	II	9	24	137	19.2
56	71	F	Breast	II	2	20	227	156
57	87	F	Breast	II	15.4	21	39.6	38
58	82	F	Breast	II	2.3	22	62.9	57.2
59	75	F	Breast	II	0.7	10	19.6	24.9
60	78	F	Breast	II	1.6	20	121	61.2
61	77	F	Breast	II	4.6	25	308	234
62	71	F	Breast	II	1.6	9.9	43.5	32
63	74	F	Breast	II	5.4	11.1	24.9	8.4
64	73	F	Breast	II	2.1	48.3	70.5	18.9
65	70	F	Breast	II	25.4	23.7	31.1	22.2
66	72	F	Breast	II	6.4	24.1	18.2	10.4
67	75	F	Breast	II	3	74.8	20.6	10.7
68	74	F	Breast	II	5.4	15.5	20.8	16.7
69	44	F	Breast	II	1.1	31.9	9.3	15.1
70	73	F	Breast	II	1.1	35.7	14.6	14.9
71	73	F	Breast	II	2.4	53	50.1	68
72	73	F	Breast	II	3.2	63.2	51.4	36.5
73	55	F	Breast	II	2.2	13.2	24.4	25.8
74	74	F	Breast	II	5.4	10.9	38.4	73.5
75	72	F	Breast	II	2.4	41.3	16.4	14.8
76	75	F	Breast	II	2.1	37.9	20.2	12.2
77	73	F	Breast	II	2.8	50.5	48.9	17.9
78	84	F	Breast	II	10.1	60.4	26.8	30.6
79	unk	F	Breast	II	2.9	45.5	67.1	27.5
80	unk	F	Breast	II	5.4	15.7	6.5	8.7
81	29	F		Normal		5.8	5.6	
82	39	F		Normal			8.2	10.2
83	39	F		Normal			53.2	80.2
84	19	F		Normal			20	14.9
85	31	F		Normal			99.8	105
86	19	F		Normal			3.3	2.5
87	22	F		Normal			17	25.2
88	47	F		Normal			27.8	31
89	29	F		Normal			33.4	19.7
90	20	F		Normal			7.9	4.5
91	20	F		Normal			23.6	40.8
92	25	F		Normal			10.9	21.4
93	39	F		Normal			5.9	11.9
94	41	F		Normal			25.5	25.8
95	53	F		Normal			6.3	15.1
96	34	F		Normal			49.1	16.1
97	27	F		Normal			20.8	14.8
98	39	F		Normal			7.9	7.2
99	33	F		Normal			7	10.2
100	45	F		Normal			51.8	52.8
101	22	F		Normal			13.3	12
102	24	F		Normal			49.9	56.1
103	31	F		Normal			4.1	3.4
104	47	F		Normal			13.9	12.9
105	51	F		Normal			9.9	8.6
106	47	F		Normal			8	9.8
107	19	F		Normal			6.8	4.5
108	43	F		Normal			16.2	14.4
109	37	F		Normal			24.4	9.8
110	27	F		Normal			5.5	4.6
111	32	F		Normal			9.3	4.6
112	42	F		Normal			16.3	12.8
113	21	F		Normal			3.1	4
114	27	F		Normal			5.5	4.8
115	30	F		Normal			13.7	9.9
116	31	F		Normal			9.3	7.5
117	34	F		Normal			3.8	5.2
118	53	F		Normal			3.8	4.3
119	52	F		Normal			7.5	9.8
120	36	F		Normal			30.5	73.2

Table XIV. *Breast cancer response to therapy.*

#	Age/ DODX	MPS E1	MPS E2	Histology	Stage	Grade	DODX	DOD	# DAYS	TRMT	Drug(s)	Status	CEA	15-3	Site
44	77	58.6	34.4	Ductal adenocarc.	IV	4	10/8/87	17/11/94	d2289	Chemo	Novantrone	Stable	2.8	18	Breast
43		65.6	27.2	Ductal adenocarc.	IV	4		13/12/94	d2315		Novantrone	Stable	2.5	68	Breast
42		9.6	39.3	Ductal adenocarc.	IV	4		13/12/94	d2315		Novantrone	Stable	2.5	68	Breast
45		75.6	39.9	Ductal adenocarc.	IV	4		10/1/95	d2343		Novantrone	Stable	2.4	46	Breast
41		27.8	18.1	Ductal adenocarc.	IV	4		7/2/95	d2371		Novantrone	Stable	2.6	43	Breast
57	66	44.6	26.8	Ductal adenocarc.	IV	3	18/6/94	5/10/94	109	None		Stable	0	37	Breast
58		74.4	78.5	Ductal adenocarc.	IV	3		26/10/94	130	None		Stable	0	32	Breast
59		81.1	70	Ductal adenocarc.	IV	3		4/1/95	200	None		Stable	0	37	Breast
49	73	34	30.8	Ductal adenocarc.	III	3	29/10/93	25/5/95	580	Chemo	Adriamycin	Progres	0	39	Breast
50		27.6	14.8	Ductal adenocarc.	III	3		15/6/95	601		Adriamycin	Progres	0	49	Breast
51		35.1	23.3	Ductal adenocarc.	III	3		5/7/95	621		Adriamycin	Progres	14.9	66	Breast
60	66	76	127	Ductal adenocarc.	IV	3	19/3/91	4/10/94	1294	Chemo	Cytoxan/	Stable	5.6	18	Breast
61		334	259	Ductal adenocarc.	IV	3		25/10/94	1315		Methotrexate	Stable	6	16	Breast
62		175	161	Ductal adenocarc.	IV	3		3/1/95	1385		/5FU	Stable	5.3	13	Breast
63		365	336	Ductal adenocarc.	IV	3		31/1/95	1413			Stable	5	18	Breast
64		307	346	Ductal adenocarc.	IV	3		28/2/95	1441			Stable	3.6	13	Breast
68	62	210	273	Ductal adenocarc.	III	3	20/1/93	23/6/95	855	Chemo	Leucovorin/	Stable	7.5	1760	Breast
69		227	183	Ductal adenocarc.	III	3		19/7/95	881		5FU	Stable	6.8	1290	Breast
70		332	282	Ductal adenocarc.	III	3		28/7/95	890			Stable	6	860	Breast
52	56	67.6	40.9	Ductal adenocarc.	II	2	7/9/94	4/1/95	119	Chemo	Cytoxan/	Stable	2.3	40	Breast
53		14.5	9.6	Ductal adenocarc.	II	2		11/1/95	126		Adriamycin/	Stable	2.2	35	Breast
54		24.8	19.7	Ductal adenocarc.	II	2		25/1/95	140		5FU	Stable	1.9	29	Breast
55		92.3	76.5	Ductal adenocarc.	II	2		21/2/95	174			Stable	1.7	23	Breast
56		63.6	42.9	Ductal adenocarc.	II	2		21/3/95	203			Stable	0	35	Breast
65	50	50.8	40.5	Adenocarcinoma	III	3	7/5/92	7/6/95	1126	Chemo	5FU/Cytoxan	Progres	9.5	280	Breast
66		101	92.2	Adenocarcinoma	III	3		21/6/95	1140		/Methotrexate	Progres	10.3	660	Breast
67		56.1	53.5	Adenocarcinoma	III	3		5/7/95	1154			Progres	11.6	840	Breast
36	49	82.5	99.8	Adenocarcinoma	III/IV		9/12/92	23/11/94	714	None	None	Progres	9.3	162	Breast
37		42.1	58.3	Adenocarcinoma	III/IV			24/2/95	807	Horm	Tamoxifen	Respon	12.4	143	Breast
38		34.6	44.3	Adenocarcinoma	III/IV			31/3/95	843		Tamoxifen	Respon	9	76	Breast
39		57.4	41.1	Adenocarcinoma	III/IV			24/5/95	897		Tamoxifen	Stable	9.6	51	Breast
40		46.7	31.2	Adenocarcinoma	III/IV			5/7/95	939		Tamoxifen	Stable	7.6	56	Breast
46	51	25.1	20.1	Adenocarcinoma	I		20/4/94	10/11/94	205	Horm	Novaldex	Stable	0.5	21	Breast
47		16.7	11.8	Adenocarcinoma	I			12/1/95	268		Novaldex	Stable	0.6	7	Breast
48		12.6	7.1	Adenocarcinoma	I			20/2/95	307		Novaldex	Stable	0.5	24	Breast
71	48	133		Adenocarcinoma	I		15/7/94	6/6/95	326	Horm	Novaldex	Stab (Ned)	6.4	16	Breast
72		59.5		Adenocarcinoma	I			11/8/95	392			Progres	12.9	41	Breast
73		90.5		Adenocarcinoma	I			6/9/95	418			progres	16.1	61	Breast
74		58.7		Adenocarcinoma	I			31/10/95	456			Progres	33	132	Breast
75		69.2		Adenocarcinoma	I			15/11/95	471			Progres	30.6	73	Breast
31	64	42.5	27.4	Adenocarcinoma	B	3	8/10/92	8/11/94	761	Chemo	Leucovorin/	Progres	29.1	15.6	Rectum
32		25.7	20.7	Adenocarcinoma	B	3		8/12/94	791		5FU	Respon	17.2	14.9	Rectum
33		123	85.3	Adenocarcinoma	B	3		12/1/95	826			Respon	10.9	11.1	Rectum
34		13	11	Adenocarcinoma	B	3		9/2/95	854			Respon	11.5	12.2	Rectum
35		8.6	14.6	Adenocarcinoma	B	3		20/3/95	894			Progres	18.7	11	Rectum

Future Prospects

The information presented here, with a large panel of benign diseases, a larger panel of early stage cancers, and longitudinal studies provide substantial preliminary evidence about the potential efficacy of the MPS-1 test in the early detection of a broad spectrum of oncogenic processes.

It is worth noting here, that healthy individuals with MPS-1 levels <10 and lower, were free of cancer (>99.0%) by standard imaging methods such as CAT, MRI, or PET. Thus, the likelihood of cancer in subjects with <10 ng/mL of MPS-1 in the serum correlates with the absence of cancer with a correlation coefficient of $p<0.001\%$. Therefore, it is conceivable that the MPS-1 test may be useful to detect

numerous types of malignancies in early stages of development, thereby reducing the mortality and morbidity rate from various types of cancers, and thus the enormous expenditures associated with negative imaging diagnosis and various cancer treatments used in advanced cancer. Levels lower than 10 ng/mL appear to indicate in a large series of subjects the absence of any type of carcinogenic process as described in this extensive article with various cancer types.

Quality criteria. As can be calculated from total distribution of MPS-1 values shown in the Tables, the quality criteria of the MPS-1 test as a tumor marker, characterized by its diagnostic specificity, sensitivity, and the cutoff value indicate that the MPS-1 test has high specificity (>75%) and sensitivity (>89%), as a tumor marker. However, the MPS-1 test cannot identify the site of origin of the tumor. Thus, it should be used in combination with other physical techniques such as CAT, MRI, PET. Thus, low levels of MPS-1 (<10 ng/mL) indicate with high probability that the individuals are most likely free of cancer disease, and thus, further screening with CAT, MRI and PET could be avoided.

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