AMAS® cancer test
anti-malignin antibody in serum

An innovative aid in early cancer diagnosis and followup

Oncolab™
1-800-9CA-TEST

The AMAS test measures serum levels of AMA, an antibody found to be elevated in most patients with a wide range of active non-terminal malignancies.

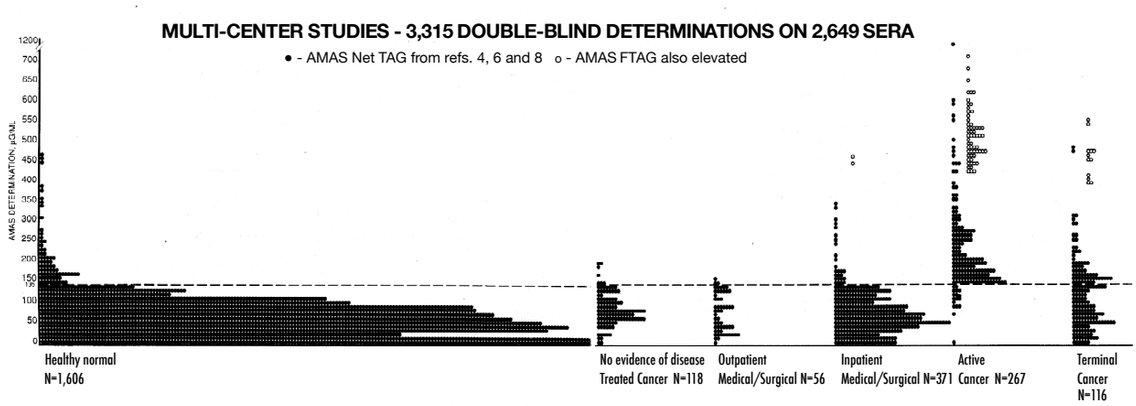
All of the data, from both Bogoch et al. (ref.4) and from the independent study performed by SmithKline Laboratories (ref.6) support the fact that the AMA (Anti-Malignin Antibody) is elevated almost regardless of the site or cell type of the malignancy; that is, AMA is a general transformation antibody, not just for one particular kind of cancer. For sera shipped overnight, false positives are 5% and false negatives 7% (3,315 double-blind tests of patients and controls, refs. 4, 6 and 8).

This test measures levels of a specific antibody, not an antigen.

AMA is the antibody to Malignin, a 10,000 Dalton polypeptide which has been found to be present in most malignant cells regardless of cell type or location (refs.1 to 8). Unlike tests such as CEA, which measure less well-defined antigens whose serum levels tend to be inconstant but elevated late in the disease, the AMAS test measures a well-defined antibody whose serum levels rise early in the course of the disease. In some cases, the AMAS test has been positive (elevated) early, i.e. 1 to 19 months before clinical detection. On the other hand, since antibody failure often occurs late in malignancy, elevated antibody is then no longer available as evidence of the presence of antigen and therefore, late in the disease, the AMAS test cannot be used as a diagnostic test, but may be useful for monitoring (ref.4).

The AMAS test may be useful as a diagnostic aid.

A common clinical situation involves signs or symptoms suggesting a disorder which may or may not be malignant. While neither AMAS nor any other clinical laboratory test can by itself answer this question, AMAS test results may help the physician in the diagnostic process. The double-blind clinical studies in the graph below include non-cancer control groups and malignancies of the breast, lung and brain as well as melanomas, lymphomas, leukemias, and colorectal malignancies. Also included are smaller numbers of malignancies of the larynx, uterus, cervix, ovary, anus, stomach, esophagus, prostate, bladder, urethra, kidney, testis, thyroid, and skin and fibrosarcoma, leiomyosarcoma, osteogenic sarcoma, rhabdomyosarcoma, mesothelioma, liposarcoma and hemangioblastoma (see graph on multi-center studies, below).

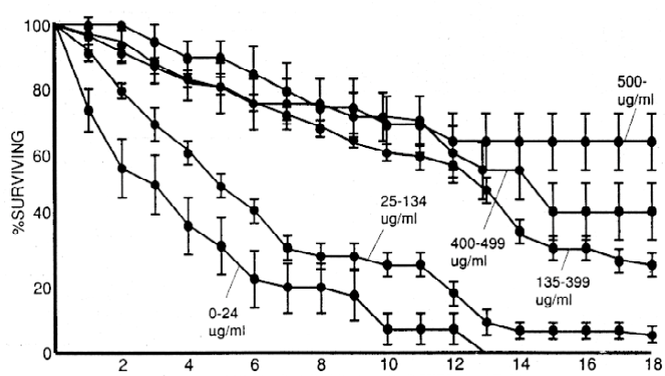


Cancer subgroups are defined as follows: No Evidence of Disease/Treated Cancer - treated successfully 1 to 15 years before AMAS determination; Active Cancer - alive one year after determination; Terminal Cancer - deceased within one year of determination.

Monitoring and the quantitative relationship of AMAS to survival.

Both monitoring data (ref.4) and a retrospective survival study of 511 cancer patients (ref.6) have shown that the AMAS test may be useful in indicating disease progression and prognosis. Thus in known cancer patients, when the immune response is good as evidenced by high antibody levels, the prognosis is good; and when the antibody level falls, the prognosis is poor.

Anti-Malignin Antibody is the first general cancer antibody found to relate to patient survival. The test therefore may be useful as an adjunct to standard (sometimes less accurate) staging information such as the spread of malignancy beyond the capsule of the primary organ and the presence of metastases in lymph nodes, or general symptoms such as anemia, weight loss and fatigue.



ACTUARIAL SURVIVAL IN FOLLOW-UP OF CANCER PATIENTS

AMAS® cancer test
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How do I get tested?

Please ask your doctor. Physicians around the country are recommending and administering the AMAS test on a regular basis for patients at high risk for cancer, and for followup purposes on patients already diagnosed and/or treated for cancer. If your doctor is not familiar with the test and does not have a shipping kit, please call and we can send a free kit. The kit contains reprints of scientific papers on the test a requisition form, and all supplies for drawing and sending a blood serum sample. The kit includes a Styrofoam packing box and silicone-free test tubes, as well as step-by-step instructions for the lab. The only other requirements are a centrifuge and a local supplier of dry ice for shipping. Your doctor should receive the results within 72 hours of our receiving the serum sample.

Is this covered by Medicare and insurers?

The AMAS test is covered by standard Medicare reimbursement to Oncolab. While we do not work directly with private insurers, HMOs or PPO plans, we can provide you with a receipt which you may be able to use to get reimbursement from your provider.

Limitations and Warnings

1. The low false-positive and false-negative rates have permitted successful screening in selected high-risk populations, as in chemical workers (ref.8) and in the preclinical detection of cancer in 2.3% of medical-surgical cases (ref. 4) but the efficacy of screening in larger normal populations has yet to be determined.

2. A normal AMA level can occur in non-cancer, in advanced and terminal cancer, and in successfully treated cancer in which there is no further evidence of disease; clinical status must be used to distinguish these states.

3. As in all clinical laboratory tests, the AMAS test is not by itself diagnostic of the presence or absence of disease, and its results can only be assessed as an aid to diagnosis, detection or monitoring of disease in relation to the history, medical signs and symptoms and the overall condition of the patient.

Performance Characteristics

Anti-Malignin Antibody is elevated in 93-100% of cases in which active non-terminal malignancy is the clinico-pathological diagnosis; overall asymptomatic ('false') positives are 5% in sera kept shipped overnight (refs.4-8). AMA is normal in 96% of cancer patients who no longer have evidence of disease (refs.4, 6). Within-run, inter-technician-same-lab, and inter-lab variability are low, as reported in the Smith-Kline study (ref.6).

Every AMAS test is run under rigorous quality control. Control solutions containing known amounts of standard monoclonal AMA are run with each test. AMA, when produced in vivo as mouse (ref.3) or as human (ref.7) immunoglobulin, and when isolated from human serum (ref.7) is predominantly IgM. Target® reagent shelf life is as long as 7 years.

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