

Evidence Table

Clinical Area: Anti-malignin antibody test.

Reference: Thornthwaite JT. Anti-malignin antibody in serum and other tumor marker determinations in breast cancer. *Cancer Letters* 2000;148:39-48.

Study Type: Comparison of diagnostic tests.

Study Aim: To determine if tumor markers aid the diagnosis of breast cancer, and monitoring of the residual disease.

Outcomes

- *Primary:* Sensitivity, and specificity of antimalignin antibody in diagnosing breast cancer.

Design

- *Number of subjects:* N=230 (n=154 healthy volunteers, and 76 patients with suspicious mammogram or history of breast cancer).
- *Description of study population:* Patients and controls were all recruited from Baptist Hospital, Miami, Florida. Healthy volunteers: Ages ranged from 25-70 years (mean 43 ± 100, 52% women. Patients: 33 (43.5%) patients had no tumor mass (10 with no evidence of disease, 18 with microcalcifications, and 5 with fibrocystic disease), 11 (14.5%) patients had measurable tumor mass and negative pathology, and 32 (42%) had measurable tumor mass and positive pathology. Patients' characteristics were not provided.
- *Inclusion /exclusion criteria:* Not discussed.
- *Power:* Not discussed.
- *Procedure:* Study participants were tested with serum antimalignin antibodies (AMAS) test in duplicates, and cancer antigen tests (CEA, CA 15-3, CA 19-9 and CA 125 assays).

Validity:

- *Independent blind comparison with a gold standard or follow-up of those not receiving the gold standard test?* The gold standard was histopathology. Laboratory personnel were blinded to the clinical diagnosis, and the pathologists were blinded to the laboratory assays results.
- *Was "normal" defined?* Yes.
- *Appropriate spectrum of disease?* Yes.
- *Consecutive patients?* Not discussed.
- *Methods described in enough detail to enable you to replicate the test?* Yes.
- *Reproducible results?* ??.

- **Conclusions regarding validity of methods:**

The authors did not provide any data on how the patients were selected for the study, the inclusion/exclusion criteria, power analysis, or patients' characteristics.

Results:

Mean AMAS values* for the study participants

	N	Mean AMAS value \pm SD
Healthy volunteers	154	76 \pm 23
Patients with no tumor mass**	33	108 \pm 21
Patients with tumor mass and negative pathology**	11	137 \pm 60
Patients with tumor mass and positive pathology	32	220 \pm 64

* Serum antimalignin antibodies, negative values range 0-134 μ g/ml, borderline 100-134 μ g/ml (this was designated as normal if it was \leq 134 on a second test), and positive $>$ 135 μ g/ml (according to earlier studies)

**With suspicious mammogram, or history of breast cancer.

Sensitivity of AMAS and other cancer antigen tests:

Test	Sensitivity for breast cancer
AMAS*	97%
CEA	0%
CA 15-3	10%
CA 19-5	5%
CA 125	16%

Specificity of AMAS:

False positive 0.7% (1/154) among the healthy volunteers

False positive 9.1% (4/44) among patients with tumor mass and negative pathology

Calculated specificity based on these figures is 97.5% (calculated by reviewer).

Change in AMAS after primary tumor removal:

Data presented in graph forms indicates that AMAS value drops within a week of the primary tumor removal.

Authors' Conclusions:

The authors concluded that the AMAS test was very precise and reliable, and more sensitive in detecting breast cancer than other cancer antigen tests. They noted however, that the study does not address the use of the test as a screening tool.

Reviewer's Conclusions:

The study compared AMAS testing for breast cancer with histopathology as a gold standard, and with other cancer antigens tests. The authors noted that the cut off values and ranges at which the test was designated as positive or negative were based on previous studies, with no indication that they were validated. The study was relatively small (only 32 patients had positive pathology), the authors did not discuss any inclusion/exclusion criteria, and how the patients and controls were selected, and did not provide data on patients' characteristics.