

**BIOMARKER AND ALPHA-1-ANTITRYPSIN TUMOR ANTIGEN FOR USE IN DIAGNOSTICS AND IMMUNODIAGNOSTICS IN EARLY STAGE BREAST CANCER**

<i>Offering Organization:</i>	Centro de Investigación y Asistencia en Tecnología y Diseño del Estado de Jalisco, A.C.
<i>Type of Organization:</i>	Public Research Center
<i>Development Stage:</i>	Industry Pilot
<i>Desired Relationship:</i>	<ul style="list-style-type: none"> <li>– Technological research and development financing (technological partner)</li> <li>– Specialized application tests</li> <li>– Creation of a new company (Joint Venture) for the commercialization of the products outlined herein</li> <li>– Licensing of patents</li> </ul>
<i>Sector:</i>	Biotechnology
<i>Area of knowledge:</i>	Medicine
<i>Key words:</i>	Breast Cancer, Biomarker, Antigen, Alpha 1-Antitrypsin Tumor, A1AT, Cancer Stage

**DETAILED DESCRIPTION:**

*Problem to be solved :*

Breast cancer is one of the most common malignancies in women and it is the leading cause of death from cancer worldwide, with an incidence rate of 1.1 million cases annually. For this reason, early detection of breast cancer is extremely important. The use of mammography has proved effective; there has been a reduction in mortality of 20% to 35% in women between the ages of 40 and 69 years. The predictive value of mammography is however decreased when patients have denser breast tissue, small lesions or are pre-menopausal.

*Solution:*

This current invention, a biomarker which is applicable in the biomedical technology field, identifies and classifies cancer stages in patients. It specifically detects autoantibodies in patients in the early stages of breast cancer in order to distinguish them from healthy patients. The biomarker is used as an autoantigen to detect autoantibodies in the patient's serum via immunoassays. This biomarker will prevent patients from reaching a more advanced cancer stage (stage III and IV). This will increase survival rates, reduce mortality rates, and consequently reduce costs.

*New and Innovative Aspects:*

The results suggest that the A1AT and antibodies used against this protein are good indicators for detecting breast cancer and diagnosing it in early stages.

**TECHNICAL CHARACTERISTICS:**

It has been demonstrated that the serum from cancer patients contains antibodies that react with autoantigens called tumor-associated antigens (TAA). An immunoproteomics study was done of 25 serums of breast cancer patients in stage II and 20 serums of healthy donors to detect the TAAs. The pre-classified serum samples were subjected to 2DE and were transferred to nitrocellulose membranes (NC). These were incubated with serum from both patient groups. When comparing the 2D Western Blot patterns you can

see that three proteins were from healthy patients. All three proteins obtained from the 2D gels were analyzed using MALDI-MS. The results show that the protein is Alpha-1-antitrypsin (A1AT). A 1DE Western blot analysis was performed to confirm the presence of protein A1AT antibodies in the patients' serums. It was detected in 24 of 25 (96%) breast cancer patients and 2 of 20 (10%) in the control group. Our results suggest that using A1AT and antibodies against this protein are useful as indicators in breast cancer screenings and in diagnosis in the early stages.

*Main advantages derived from its utilization:*

- This biomarker identifies and classifies cancer stages in patients in the early stages of breast cancer in order to distinguish them from healthy patients.
- This biomarker will prevent patients from reaching a more advanced cancer stage (stages III or IV). This will increase survival rates, reduce mortality rates, and consequently reduce costs.
- This biomarker can be used when mammography is not effective, for example, when patients have dense breast tissue, small lesions or are pre-menopausal.

*Applications:*

- Breast Cancer

**INTELLECTUAL PROPERTY**

- Patent application filed in 2010
- Patent application number: MX/a/2010/014331

**ABOUT THE OFFERING ORGANIZATION**

*Presentation:*

El Centro de Investigación y Asistencia en Tecnología y Diseño del Estado de Jalisco, A.C. (CIATEJ) is a public research center that belongs to the national technology development and innovation network, the National Council for Science and Technology (CONACyT). CIATEJ is focused on the agricultural, food, health, and environmental sectors with an emphasis on the application of innovative biotechnology.

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