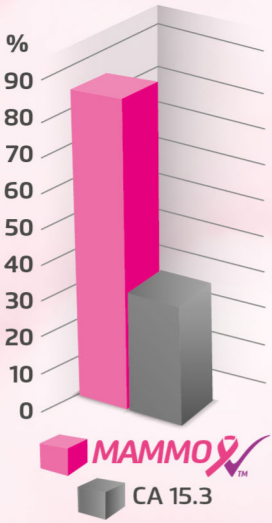

MAMMOSITE™
The only solution
for the surveillance
and monitoring of early
breast cancer recurrence
MILAGEN

MAMMOX™

Is a new diagnostic product developed precisely for **breast cancer** (**BC**) survivors. it allows routine surveillance and monitoring of women who had **BC** and warns them of the disease recurrence **years ahead of time**, so they can take preventive measures to fight it off in time before it spreads to other important organs.

MAMMOX is up to 4x more effective than CA15.3, the standard of care for **BC** monitoring. The graphic data below shows the effectiveness of *MAMMOX*.



MAMMOX is a blood-based test that measures the concentration of a specific protein released by cancer cells in the blood.
It can be performed regularly to ensure the absence of the disease without fear of the unexpected.

BENEFIT OF *MAMMOX*

The early detection of **BC** ensures easy control of the disease and a **95%** chance of survival rate. If the disease is discovered at a later stage, the likelihood of managing it becomes much harder, reducing the life expectancy and affecting the quality of life.

THE EARLIER THAT BREAST CANCER RECURRENCE IS DETECTED AND TREATED, THE BETTER THE CHANCE OF A POSITIVE OUTCOME. EARLY DETECTION OF CANCER RECURRENCE CAN BE LIFE-SAVING.

WHO CAN BENEFIT FROM *MAMMOX*?

Presently, there is no effective procedure for BC surveillance. In the US, there are close to 4 million women living with **BC** who have received primary treatment.

These cancer patients remain indefinitely at risk of cancer recurrence. They can all benefit from *MAMMOX* via routine monitoring for the better management of their health.

BREAST CANCER AND STANDARD OF CARE

Presently, there are almost 4 million breast cancer survivors at permanent risk of developing cancer recurrence because there is no effective procedure to monitor

their health status once they finish primary treatment.

The **CA15.3** is the current cancer marker in use in clinics for **BC** survivors. Unfortunately, this marker is not effective to monitor cancer recurrence. It is expressed only in **24%** of breast cancer survivors when they are in the late stage of the disease and developing metastasis in different organs such as bone, liver, and lung.

Other serum markers such as **CA 19** and **CA 27** are used for **BC** survivors but they lack both specificity and sensitivity, which leaves patients with no effective solution for monitoring and at permanent risk of disease recurrence.[4]

SURVEILLANCE IS A HEALTH PRIORITY IN BC SURVIVORS

BC patients remain indefinitely at risk for local and/or systemic recurrence. **Guidelines specifically recommend against the use of serum markers CA15-3 and CEA** for routine monitoring of early BC recurrence in asymptomatic patients.[1]

At present, surveillance of disease recurrence in **BC** survivors relies on annual mammography screening, regular physical examination, and follow-up every 3-6 months for the first 3 years after primary therapy, then every 6-12 months for the next 2 years, and annually thereafter, according to the ASCO/ACS joint clinical practice guidelines.

A substantial proportion of patients do not follow surveillance guidelines due to the poor efficacy of current procedures.

MUTATED CIRCULATING DNA FRAGMENTS FOUND IN THE BLOOD ARE NOT NECESSARILY CANCER-RELATED.

Recent liquid biopsy tests are based on tiny circulating tumor DNA (ctDNA) fragments in the blood. These tests suffer from a lack of sensitivity, specificity, and other technical issues including irreproducibility of results from the same patient specimen.[2] Abundant literature highlights the clinical limitations in the utility of ctDNA. Some limitations include:

1. Huge amounts of circulating DNA, unrelated to cancer, are released into the bloodstream constantly as cells in our body naturally become old and die as part of the natural cellular cycle of growth, aging and replacement.
2. Healthy individuals can have mutations in their DNA as a result of environmental exposure (pollution, toxic materials, foods, etc...) and the natural aging process.
3. Cells isolated from the same biopsy of the same patient can differ substantially from one another genetically. Even within one patient, the tumor cells that make it into circulating blood vary drastically.[3,4]
4. Mutations are also found in bone marrow progenitor and hematopoietic cells that are unrelated to cancer mutation but can complicate further the interpretation of mutations found in circulating DNA in the blood and can be wrongly attributed to cancer.[5,6]

ctDNA CONCLUSION

Making recommendations to patients about their disease status and therapeutic interventions based on the genetics of heterogeneous cancer cells that evolve **and change CONSTANTLY begs the question of the real clinical value of ctDNA!**

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Milagen's Clinical Laboratory is certified under the **Clinical Laboratory Improvement Amendments** of 1988 (**CLIA**) and accredited by the **Commission on Office Laboratory Accreditation** (**COLA**).

MAMMOX performance characteristics were determined by **Milagen**, Inc. The *MAMMOX* test has not been cleared or approved by the FDA yet. **Milagen's** Clinical Laboratory is regulated under **CLIA** to perform high-complexity testing.
Milagen's CLIA registration is **CLIA ID# 05D2269442**.

Milagen Clinical Laboratory and headquarters are located at **1255 Park Ave., Suite B, Emeryville, CA 94608-3679. USA.**

https://milagen.com

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