




# MILAGEN

**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)**.

**Milagen's** Clinical Laboratory is regulated under **CLIA ID No: 05D2269442**, to perform high-complexity testing. The **IGOX** test and its performance characteristics were determined by **Milagen, Inc.** The **IGOX** diagnostic test has not been cleared yet by the **FDA**.

**Milagen's** clinical laboratory and headquarters are located at **1255 Park Ave., Suite B, Emeryville, CA 94608-3679. USA.**

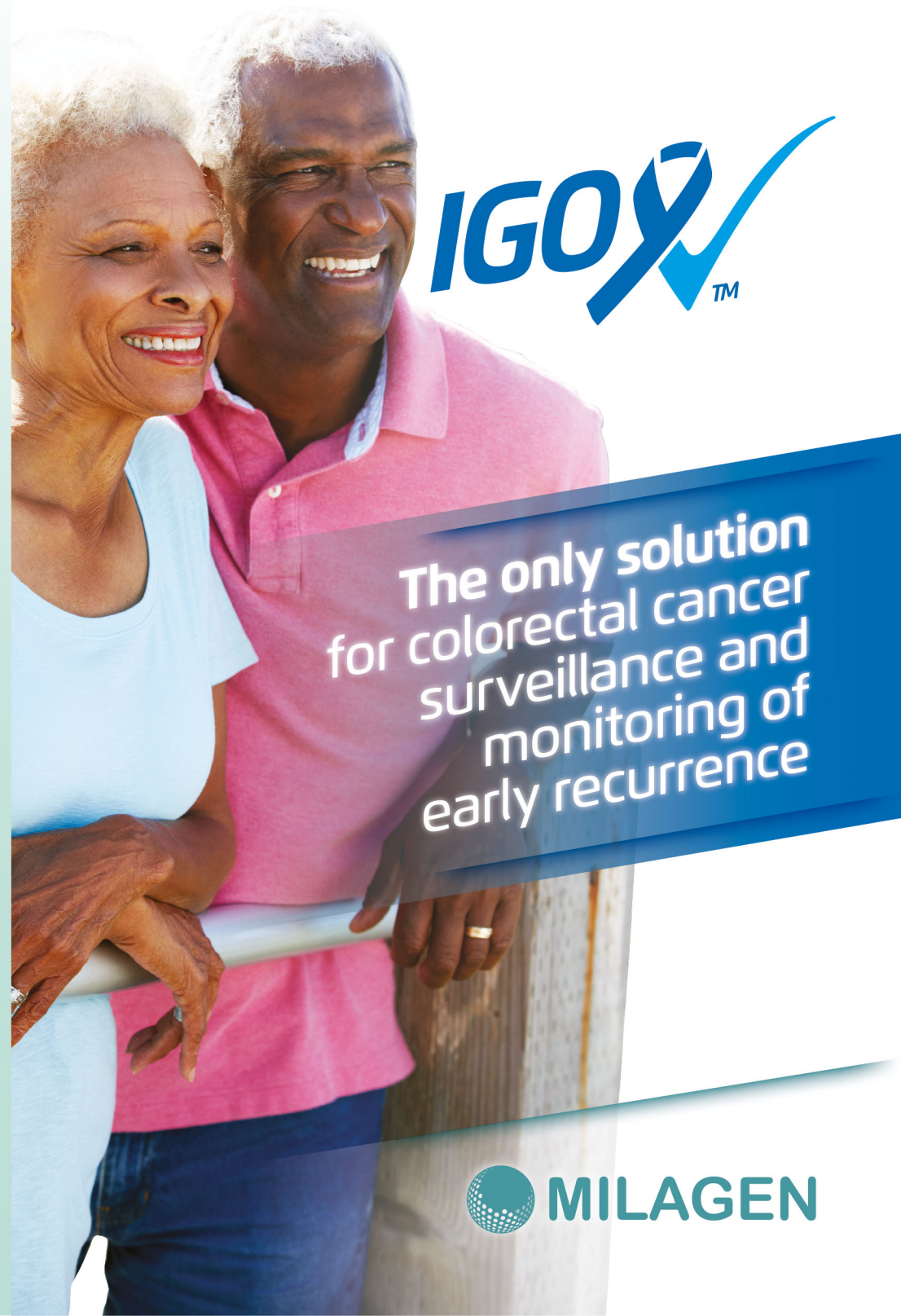



<https://milagen.com>

**REFERENCES:**


1. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6745820/pdf/CAM4-8-5574.pdf>
2. Melissa K. Accordino, et al, Serum Tumor Marker Use in Patients with Advanced Solid Tumors. ASCO. J. Volume 12/ Issue 1 / January 2016.
3. <https://www.sciencedirect.com/science/article/pii/S0098299719300846>.
4. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4514648/pdf/pone.0133830.pdf>
5. <https://med.stanford.edu/news/all-news/2012/05/not-all-tumor-cells-are-equal-study-reveals-genetic-diversity-in-cell-s-shed-by-tumors>.
6. <https://www.cell.com/action/showPdf?pii=S0092-8674%2821%2900294-4>.
7. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4245510/pdf/atm-02-11-107.pdf>.
8. <https://aacrjournals.org/clincancerres/article/24/18/4437/80899/False-Positive-Plasma-Genotyping-Due-to-Clonal>.

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The only solution  
for colorectal cancer  
surveillance and  
monitoring of  
early recurrence



# MILAGEN

21.5 cm

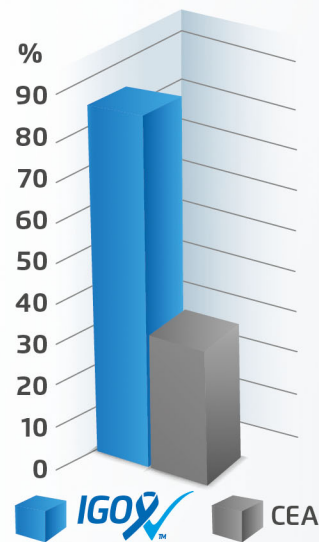




Is a new diagnostic test developed for **Colorectal Cancer (CRC)** survivors. it allows the routine surveillance of women and men who had **CRC** and warns them of possible recurrence in time, so they can take preventive measures to successfully treat the disease before it spreads to other essential organs and disrupts their normal functions.

**90% OF CANCER PATIENTS DIE FROM THE SPREAD OF METASTASIS THAT GROWS UNCHECKED INTO ESSENTIAL ORGANS AND DISRUPTS THEIR FUNCTIONS, NOT BECAUSE THEY ARE HARBORING THE DISEASE.<sup>1</sup>**

Our studies show that **IGOX** is up to 4 times more effective than the CEA test, the only blood test used in the clinic for **CRC**, despite it not being recommended for that use.<sup>2</sup> (see the graphic below).



**IGOX** is a blood-based test that measures the concentration of a specific protein released by cancer cells into the blood. It can be performed regularly in the gaps between followup visits.

**BENEFITS OF IGOX**

Early detection of **CRC** recurrence maximizes both treatment options and chance of survival. If the disease is discovered at later stages, then the likelihood of successfully managing the disease becomes much smaller, and both life expectancy and quality of life are greatly reduced.



**EARLY DETECTION OF CANCER RECURRENCE CAN SAVE LIVES. THE EARLIER THAT CRC RECURRENCE IS DETECTED, THEN THE BETTER THE CHANCE OF SUCCESSFULLY MANAGING IT.**

**WHO CAN BENEFIT FROM IGOX?**

There are almost 1.7 million people in the USA who are **CRC** survivors. These patients are indefinitely at risk of **CRC** recurrence, because until now, there is no effective, easy-to-use surveillance procedure.

**IGOX** can help detect **CRC** recurrence several years ahead of its detection by **imaging technologies**. **CRC** survivors tested regularly with **IGOX** can benefit greatly by having better oversight and management of their health condition.

Based on current knowledge and our own studies, it is recommended that **CRC** survivors conduct regular surveillance and monitoring to prevent relapse without warning and maintain vigorous control to keep the cancer at bay.

**MUTATED TINY DNA FRAGMENTS FOUND IN THE BLOOD ARE NOT NECESSARILY TUMOR-RELATED!**

Tiny circulating "supposedly tumor" DNA (ctDNA) fragments in the blood are used to assess patient cancer status. These tests suffer from a lack of sensitivity, specificity, and other technical issues such as **RESULTS IRREPRODUCIBILITY WITH SAME PATIENT SPECIMEN**.<sup>3</sup> 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 differ substantially from one another genetically. Within one patient, the tumor cells that make it into the blood vary drastically.<sup>4,5</sup>
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.<sup>5-8</sup>

**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**!

