

Press Release

FDA Grants Breakthrough Device Designation to Amadix's preventive screening blood test for Colorectal Cancer

- PreveCol®, a blood test for oncological diagnosis, has obtained US recognition for its efficacy in detecting precancerous lesions compared to existing alternatives in the United States.
- Amadix becomes the first European company to announce this recognition for early detection of colorectal cancer.

January 23rd, Madrid, España- [Amadix, a Spanish biotech company](#), announced today that [PreveCol®](#), its colorectal cancer screening blood test, has received **Breakthrough Device Designation** from the U.S. Food and Drug Administration (FDA). With this milestone, Amadix becomes **the first European company** to announce this recognition for early detection of colorectal cancer.

PreveCol® has demonstrated to have the potential to offer a great significant **benefit to patients** and has proven to have **better diagnostic efficacy** than currently approved colorectal cancer screening tests in the US.

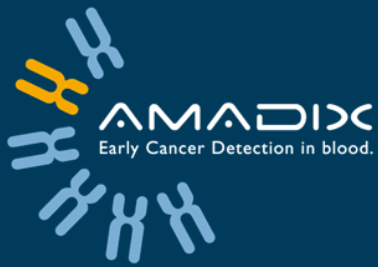
FDA's [Breakthrough Devices Program](#) is intended to provide patients and health care providers with timely access to novel medical devices by **expediting the assessment and premarket approval process**. The Breakthrough Devices Program reflects the FDA's commitment to device innovation leading to more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases.

*“To gain this recognition from the FDA is **an important milestone for our company**. It motivates us to continue working to bring PreveCol® to American patients as soon as possible. We will continue preventing the onset of colorectal cancer and the complications derived from the current treatments.”*, said Rocío Arroyo, Amadix CEO.

About PreveCol®

PreveCol® is aimed at the **early detection** of biomarkers **in blood** associated with colorectal neoplasia. The Spanish test is indicated to screen adults of either sex, **45 years or older**, without apparent symptoms.

A positive result may indicate the presence of colorectal cancer and/or Advanced Precancerous Lesions and should be followed by diagnostic colonoscopy.



→ [More information](#)

About Amadix

AMADIX is a leading molecular diagnostics company focused on liquid biopsy, developing innovative diagnostic tests for early cancer detection in blood. The mission of the company is extending people's lives, developing disruptive technologies to detect the tumor years in advance before the symptoms appear.

<https://amadix.com/>

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