

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.

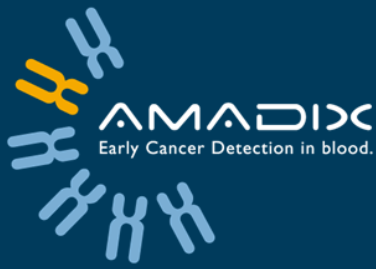
January 23rd, Madrid, España- [Amadix, a Spanish biotech company](#), announced today that [PreveCol®](#), its colorectal cancer screening blood test, has received **Breakthrough Device Designation** from the U.S. Food and Drug Administration (FDA). With this milestone, Amadix becomes **the first European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