PreveCol® SERVICE INFORMATION LEAFLET

1. General Information about PreveCol®

PreveCol® is a service designed to facilitate the detection of colorectal cancer and/or precancerous lesions. The service offered consists of the provision of extraction centres and laboratories collaborating with Amadix where blood collection and biomarker analysis will be performed. ADVANCED MARKER DISCOVERY, S.L. (hereinafter, AMADIX), using its own in vitro diagnostic software (CE marked) will analyse the expression of these biomarkers, together with certain clinical factors, by means of a proprietary algorithm. The result of this analysis will be delivered in a Results report, which will include recommendations on the next steps to be taken. PreveCol® is a diagnostic support service and does not replace colonoscopy as the reference diagnostic method.

This service is indicated for people of average risk, of either sex, **aged between 50 and 75** (both inclusive).

2. Procedure

To perform the PreveCol® service, you must go to one of the approved collaborating collection centres, where a blood sample (approximately 10 ml) will be taken. If the sample is not optimal in quality or quantity, a new collection will be requested at no additional cost.

Once you have the results report, it is recommended that you go to your doctor with this report and your clinical history for the correct interpretation and determination of the necessary measures.

3. Possible Risks

The associated risks are the usual risks of a blood collection: pain at the puncture site, slight bleeding, dizziness, fainting, infection (rare) or abnormal scarring in the case of multiple punctures.

4. Results Report

The result will be quantitative (positive or negative). Starting from the blood sample, an analysis of biomarkers in the plasma is performed, which are determined by an immunoassay (ELISA or CLIA technology). The quantified values of the biomarkers are introduced by Amadix in the algorithm that provides the final result of the process.

The result of the report will be either positive or negative, and the meaning of this result is as follows:

- **POSITIVE:** a positive result in this test indicates the possible presence of colorectal cancer or precancerous lesion(s). In this case, it is recommended that the patient be followed up with a diagnostic colonoscopy.

- **NEGATIVE:** A negative result in this test may indicate the absence of colorectal cancer or precancerous lesion(s). In this case, continued participation in cancer screening programmes is recommended.

5. Video consultation in case of positive result

If the result is positive, the report will be accompanied by the possibility of a video consultation with a health professional, who will clarify any doubts regarding the interpretation of the result report and provide guidance on the next steps.

6. Indications and Limitations

PreveCol® is clinically validated for people aged 50 to 75 years, men or women, of average risk, which are the indications of use for which the in vitro diagnostic software used by Amadix has been clinically validated. In the cases performed outside the indications for use (due to age outside the range or clinical history or high risk), the results report will indicate with a note that this should be taken into account in the interpretation of the results report.

The results are qualitative and reflect the current status of the patient and do not by themselves constitute a clinical diagnostic element. The results obtained should be interpreted in conjunction with other clinical criteria of the individual, within the overall context of a medical consultation.
Screening tests such as the one performed through the PreveCol® service may have so-called false positive and false negative results. It is possible for a positive PreveCol® result to be followed by a negative diagnostic colonoscopy, indicating the absence of colorectal cancer and/or advanced adenomas (pre-cancerous lesions). This is called a false positive. In the same way, the opposite may occur, which is known as a false negative.

It is therefore important to confirm a positive PreveCol® result by colonoscopy, under medical supervision and follow-up, and in case of a negative PreveCol® result, to continue participating in cancer screening and early detection programmes.
Once you have the result, you can consult your doctor.

7. Responsibility

Advanced Marker Discovery S.L. (Amadix) is responsible for the information contained in the report issued with the PreveCol® software. The PreveCol® software is an in vitro diagnostic medical device with CE marking in accordance with Directive 98/79/EC, and Art. 110 of Regulation (EU) IVDR 2017/746. The use made by the contracting party of the PreveCol® service and the results obtained, as well as any possible harmful consequences arising from this use, are beyond the responsibility of Amadix. Amadix reserves the right to take appropriate legal action in the event of improper use of the aforementioned studies or analyses.

8. Voluntariness

The performance of this test is entirely voluntary, and the signing of this document constitutes your consent to undergo the analysis.

INFORMATION AND AUTHORIZATION REGARDING THE PROCESSING OF PERSONAL DATA

The patient expressly authorises AMADIX to process their personal data in accordance with Organic Law 3/2018, the General Data Protection Regulation (GDPR) and current health legislation.

The data will be used to manage the test and send the result by email to the address provided. It will be kept for the legal periods and treated with strict confidentiality. Patients may exercise their rights of cancellation, access, rectification, opposition and portability by means of a written request addressed to AMADIX (Calle Acera de Recoletos 2, 1ºB, Valladolid).