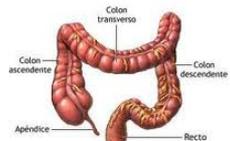


Colon cancer screening in blood

In Spain there are more than 25,000 new cases of colon cancer per year. It is the second cause of death by cancer, with a similar incidence for both men and women.

Survival depends on the stage in which the tumour is detected. Therefore screening is fundamental. However, just 12% of the adult population takes part in colon cancer population screening programmes.

The average population at risk that should take part in colorectal cancer screening programmes are men and women over 50 with no symptoms or who are apparently healthy, and with no other additional risk factors (personal and/or familial).



If colon cancer is detected in the early stages, the healing rate is over 90%.

Septina9

The analysis is performed in peripheral blood and consists in detecting the methylated form of the Septin 9 gene ($mSEPT9$). The $mSEPT9$ passes into the blood in the form of free DNA and is detected in plasma in over 90% of colon tumours. It is therefore a new genetic tumour marker. As a result, the presence of $mSEPT9$ in blood indicates the possibility of there being a neof ormation related to colon cancer.

Methylation of the Septin 9 gene is an early process in the development of the tumour, so screening is positive even in the early stages and in different colon cancer locations.

Advantages of the $mSEPT9$ test

$mSEPT9$ offers many advantages over other present colon cancer screening methods, such as faecal screening tests, sigmoidoscopy and colonoscopy.

This is an analysis that is minimally invasive; that does not breach a patient's privacy or require preparation or previous special dietary adjustment; that has a high sensitivity and specificity; and which detects all kinds of colorectal cancer, regardless of its localization.

The second generation of the **Septina9** (Epi *proColon* 2.0) has 99.3% specificity, 80.6% sensitivity, 99.9%

negative predictive value and 45.7% positive predictive value.

Therefore, $mSEPT9$ shows much better results than the present faecal screening techniques. It is an analysis that it is easy to repeat every year or two years, which improves the test's acceptance by the patients and their adherence to colon cancer screening programmes.

Indications

The analysis is recommended in:

- General population, both men and women, symptom-free, over 50 years of age
- People who do not have routine colonoscopies, as established by colorectal cancer screening programs

The analysis is not advisable in pregnant women, as $mSEPT9$ also seems to play a role in normal embryo development.

The analysis does not replace colonoscopy, which is still the diagnostic test recommended for identifying colon cancer.

Results of the analysis

Negative result

The presence of $mSEPT9$ is not identified in the patient's plasma. The patient is classified as healthy with a probability of 99.9%. A repeat analysis is recommended every one or two years.

Positive result

The presence of $mSEPT9$ in the patient's plasma is detected, so a colonoscopy must be performed. Of every 2 patients who are positive in the test, 1 will have a colon tumour.

Requirements

Fasting or other prior conditions are not necessary.

Sample: 2 tubes of 8.5 mL total blood CPDA.

Documentation: General Test Requisition Form.