

novigenix



# Early detection of colorectal cancer

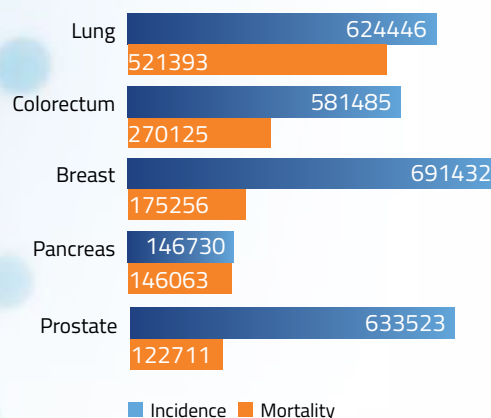
The new generation blood test: easy and effective



# COLORECTAL CANCER, A HIGH INCIDENCE RATE

- The second most deadly cancer in US & EU<sup>1</sup>
- The fourth most common cancer.
- The detection and resection of adenomatous polyps, precursors of cancer, reduce the incidence and mortality<sup>2</sup>.
- The risk of developing this cancer increases with age.

## Cancer Incidence and Mortality in US & EU<sup>1</sup>



**740** people die of colorectal cancer every day in US & EU.

**580 000** new cases are reported each year.

## EARLY DETECTION SAVES LIVES

Colorectal cancer can occur suddenly but it generally develops very slowly before the first symptoms appear. The 5-year survival rate is 85% for patients diagnosed at early stages of the cancer and 95% for patients diagnosed at the precancerous stage of adenomatous polyps.

## COLOX: AN EASY AND EFFECTIVE BLOOD TEST

- A new Swiss test for the early detection of colorectal cancer.
- A simple blood draw.
- Detects colorectal cancer and adenomatous polyps.
- Allows patients to be directed to a diagnostic colonoscopy when needed.

## THE COLOX PROCEDURE

A doctor prescribes a **Colox®** test.



The results are sent to the doctor who then informs the patient.

A blood sample is taken by the doctor or directly by the diagnostic laboratory.

INSERTED INTO  
A ROUTINE

Colox can be prescribed at the same time as other blood tests during an annual medical check-up. Consequently, the doctor has a tool to better evaluate the need for a colonoscopy.

# BASED ON AN INNOVATIVE SCIENTIFIC CONCEPT

Colox® is a molecular test which combines 29 RNA markers with 2 protein markers. RNA markers, changed during the initial stages of the development of a lesion, allow for its early detection. The protein tumor markers ensure specificity.

## VALIDATED PERFORMANCE

The performance of Colox has been validated in a multicenter clinical study in Switzerland comprising 782 people.

Product	Sample	Sensitivity	Specificity
<b>Adenomatous polyps &gt; 1cm</b>			
Colox <sup>3</sup>	Blood	52.3%	92.2% <sup>a</sup>
FIT <sup>4-6</sup> (OC-Sensor, 100ng/ml)	Stool	23.7-27.9%	94.4-97.0%
gFOBT <sup>7</sup> (Hemoccult II)	Stool	6.8%	95.2%
<b>Colorectal cancer (all stages)</b>			
Colox <sup>3</sup>	Blood	78.1%	92.2% <sup>a</sup>
FIT <sup>4-6</sup> (OC-Sensor, 100ng/ml)	Stool	69.2-75.0%	93.4-95.0%
gFOBT <sup>7</sup> (Hemoccult II)	Stool	33.3%	95.2%

## INTERPRETATION OF COLOX RESULTS

### COLOX IS NEGATIVE:

The patient has no cancerous colorectal lesion with a probability of 99.9%<sup>b</sup> (Negative Predictive Value).

Periodic testing for colorectal cancer is recommended for the patient.

### COLOX IS POSITIVE:

The patient has adenomatous polyps with a probability of 52%<sup>b</sup> but only 2%<sup>b</sup> of positive tests will be cancer (Positive Predictive Value).

A positive result requires a follow-up diagnostic colonoscopy.

## INDICATIONS AND PRECAUTIONS FOR USE

Colox® is indicated for women and men with average risk of colorectal cancer.

**Colox is not recommended for people who have a higher risk of colorectal cancer than the average with:**

- A personal history of adenomatous polyps or colorectal cancer.
- A family history of a first-degree relative with colorectal cancer.
- A family and/or personal history of a high risk hereditary syndrome such as: Lynch syndrome (HNPCC), familial adenomatous polyps (FAP), etc.
- A personal history of chronic inflammatory bowel disease (CIBD), Crohn's disease, hemorrhagic rectocolitis (HRC), etc.

**Colox is not indicated, for reasons of possible cross-reactions, for people with:**

- An inflammatory disease in an acute phase.
- Currently have, or in the past 5 years had, another type of cancer.
- Currently have, or in the past 4 weeks had, an acute infection.
- Had a physical or medical (surgical) trauma during the last 6 months.
- Received a blood transfusion during the past 4 weeks.

<sup>a</sup> Calculated using subjects with no colorectal lesions

<sup>b</sup> Simulated using subjects with prevalences of: 0.5% colorectal cancer, 9.7% adenomas ≥ 1 cm, 22% adenomas < 1 cm, 23% hyperplastic polyps<sup>8-10</sup>



## INSTRUCTIONS FOR SAMPLE-TAKING

The blood sample for the Colox® test must be processed by the laboratory within 6 hours maximum; please contact your laboratory in advance for logistical organization.

Only the Vacutainer® CPT™ (Becton Dickinson) tube provided in the Colox sample kit must be used.

The following is recommended before doing a Colox test, in order to avoid possible cross-reactions:

- No smoking for 12 hours.
- Suspend any NSAID, corticosteroid, immunosuppressant and statin treatments for a minimum of 5 times the half-life of the drug (as far as it is medically possible).

## LABORATORY PARTNERS

Colox is performed by diagnostic laboratory partners, the list is available on our website.

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### Scientific references

<sup>1</sup> International Agency for Research on Cancer - GLOBOCAN 2012

<sup>2</sup> Zauber AG *et al.* Colonoscopic polypectomy and long-term prevention of colorectal-cancer deaths. *N Engl J Med.* 2012;366:687-96

<sup>3</sup> Ciarloni L *et al.* Development and clinical validation of a blood test based on 29-gene expression for early detection of colorectal cancer. *Clin Cancer Res.* 2016 Apr 28

<sup>4</sup> Imperiale TF *et al.* Multitarget stool DNA testing for colorectal-cancer screening. *N Engl J Med.* 2014;371:187-8

<sup>5</sup> De Wijkerslooth TR *et al.* Immunochemical fecal occult blood testing is equally sensitive for proximal and distal advanced neoplasia. *Am J Gastroenterol.* 2012;107:1570-8

<sup>6</sup> Park DI *et al.* Comparison of guaiac-based and quantitative immunochemical fecal occult blood testing in a population at average risk undergoing colorectal cancer screening. *Am J Gastroenterol.* 2010;105:2017-25

<sup>7</sup> Brenner H *et al.* Superior diagnostic performance of faecal immunochemical tests for haemoglobin in a head-to-head comparison with guaiac based faecal occult blood test among 2235 participants of screening colonoscopy. *Eur J Cancer.* 2013;49:3049-54

<sup>8</sup> Quintero E *et al.* Colonoscopy versus fecal immunochemical testing in colorectal-cancer screening. *N Engl J Med.* 2012;366:697-706

<sup>9</sup> Hazewinkel Y *et al.* Prevalence of serrated polyps and association with synchronous advanced neoplasia in screening colonoscopy. *Endoscopy.* 2014;46:219-24

<sup>10</sup> Vatn MH *et al.* The prevalence of polyps of the large intestine in Oslo: an autopsy study. *Cancer.* 1982;49:819-25

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