novigenix

Early detection of colorectal cancer

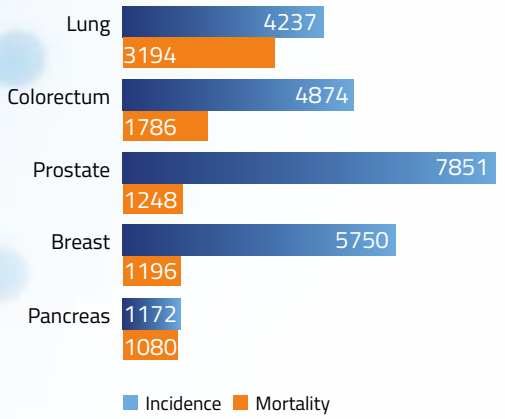
The new generation blood test: easy and effective

colox

COLORECTAL CANCER, A HIGH INCIDENCE RATE

- **The third most common cancer.**
- **The second most deadly cancer.**
- **The detection and resection of adenomatous polyps, precursors of cancer, reduce the incidence and mortality[2].**
- **The risk of developing this cancer increases with age.**

Cancer Incidence and Mortality in Switzerland[1]



5 people die of colorectal cancer every day in Switzerland.

4 800 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.

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

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

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
Adenomatous polyps>1cm			
Colox[3]	**Blood**	**52.3%**	**92.2%[a]**
FIT[4-6] (OC-Sensor, 100ng/ml)	Stool	23.7-27.9%	94.4-97.0%
gFOBT[7] (Hemoccult II)	Stool	6.8%	95.2%
Colorectal cancer (all stages)			
Colox[3]	**Blood**	**78.1%**	**92.2%[a]**
FIT[4-6] (OC-Sensor, 100ng/ml)	Stool	69.2-75.0%	93.4-95.0%
gFOBT[7] (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%[b] (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%[b] but only 2%[b] 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.

[a] Calculated using subjects with no colorectal lesions

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

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.

Scientific references

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[3] 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*

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[5] 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*

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

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

[10] 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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