Early detection of colorectal cancer

The new generation blood test: easy and effective
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 mortality².
- The risk of developing this cancer increases with age.

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.

Cancer Incidence and Mortality in Switzerland¹

<table>
<thead>
<tr>
<th></th>
<th>Incidence</th>
<th>Mortality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung</td>
<td>3194</td>
<td>4237</td>
</tr>
<tr>
<td>Colorectum</td>
<td>1786</td>
<td>4874</td>
</tr>
<tr>
<td>Prostate</td>
<td>1248</td>
<td>7851</td>
</tr>
<tr>
<td>Breast</td>
<td>1196</td>
<td>5750</td>
</tr>
<tr>
<td>Pancreas</td>
<td>1172</td>
<td>1080</td>
</tr>
</tbody>
</table>

5 people die of colorectal cancer every day in Switzerland.

4 800 new cases are reported each year.
**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.

<table>
<thead>
<tr>
<th>Product</th>
<th>Sample</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adenomatous polyps&gt;1cm</td>
<td>Blood</td>
<td>52.3%</td>
<td>92.2%</td>
</tr>
<tr>
<td>Colox³</td>
<td>Blood</td>
<td>52.3%</td>
<td>92.2%</td>
</tr>
<tr>
<td>FIT⁺⁺ (OC-Sensor, 100ng/ml)</td>
<td>Stool</td>
<td>23.7-27.9%</td>
<td>94.4-97.0%</td>
</tr>
<tr>
<td>gFOBT⁺ (Hemoccult II)</td>
<td>Stool</td>
<td>6.8%</td>
<td>95.2%</td>
</tr>
<tr>
<td>Colorectal cancer (all stages)</td>
<td>Blood</td>
<td>78.1%</td>
<td>92.2%</td>
</tr>
<tr>
<td>Colox³</td>
<td>Blood</td>
<td>78.1%</td>
<td>92.2%</td>
</tr>
<tr>
<td>FIT⁺⁺ (OC-Sensor, 100ng/ml)</td>
<td>Stool</td>
<td>69.2-75.0%</td>
<td>93.4-95.0%</td>
</tr>
<tr>
<td>gFOBT⁺ (Hemoccult II)</td>
<td>Stool</td>
<td>33.3%</td>
<td>95.2%</td>
</tr>
</tbody>
</table>

**INTERPRETATION OF COLOX RESULTS**

**COLOX IS NEGATIVE:**

The patient has no cancerous colorectal lesion with a probability of 99.9% (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% but only 2% 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 polyposis (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.

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*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 *c*"
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

1 Le cancer en Suisse, rapport 2015- Etat des lieux et évolutions. Office fédéral de la statistique 2016
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
5 De Wijkerslooth TR et al Immunochernical fecal occult blood testing is equally sensitive for proximal and distal advanced neoplasia. Am J Gastroenterol. 2012;107:1570-8