

ONCOLOGY

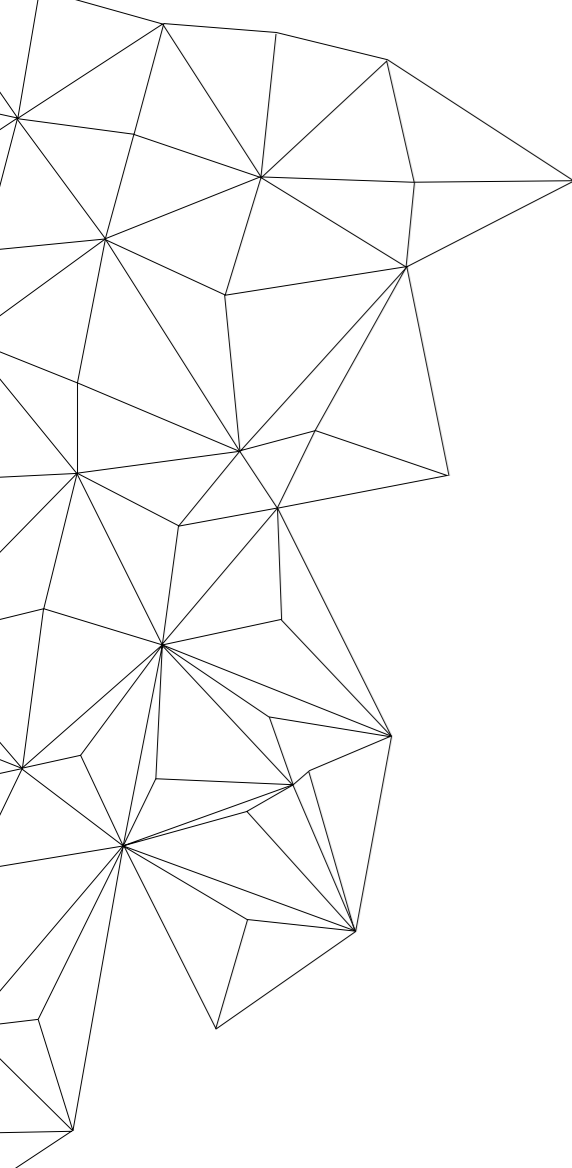
# REPORT

FIT EXTRACT FROM 1/2018

The background of the cover is a complex, low-poly geometric structure composed of various shades of gray and white, creating a sense of depth and movement. A prominent red triangle is located in the lower right quadrant, pointing towards the center.

## SUCCESS STORY FROM THE NETHERLANDS

Immunological tests  
are gaining ground



# IMMUNOLOGICAL TESTS ARE GAINING GROUND

After lung and breast cancer, colorectal cancer is the third most common cancer worldwide. To accelerate early detection, European countries are now starting to implement population-based screening programmes with FIT (Faecal Immunochemical Testing). The Netherlands has led the way for four years



Sending the FIT out to over 2 million Dutch per year: Wolfert Spijker,  
CEO Organisation for Population Screening in the Netherlands

'One of the benefits of FIT is that you can carry out high-volume testing because the throughput is fast: you can easily analyse a few thousand tests per day'

WOLFERT SPIJKER, CEO ORGANISATION FOR POPULATION SCREENING IN THE NETHERLANDS

**W**olfert Spijker, CEO of the Organisation for Population Screening in the Netherlands, is satisfied: after sending out two million tests as part of an annual colorectal cancer screening programme, over 70 per cent have been returned. Colorectal cancer was diagnosed in 4.9 out of 1,000 submissions. Usually, colorectal cancer would have remained undetected for a long time. The high submission rate is partly due to the good organisation, but also to the simplicity of the Faecal Immunochemical Test (FIT) when it comes to application and evaluation.

Globally, colorectal cancer is the third most common cancer and the second most common cancer in Europe: per year about 342,137 people develop colorectal carcinoma for the first time, and almost 215,000 die of it. The five-year survival rate is 63 per cent. Colorectal cancer accounts for around half of all gastrointestinal malignancies in Europe, 47 per cent among men and 54 per cent among women in the EU. Its burden is expected to increase by 60 per cent to more than 2.2 million new cases worldwide and 1.1 million cancer deaths by 2030. The appearance of colorectal cancer and the mortality rate vary worldwide and depend greatly on the stage of development of each country. The more developed the country

is, the more it manifests itself. A person's lifestyle is considered the main risk factor for colorectal cancer: obesity, lack of exercise, tobacco use and an unhealthy diet favour tumour formation. About one third of all cases can be traced back to genetic factors.

#### EARLY DETECTION IS WHAT COUNTS!

90 per cent of tumours in the colon develop from benign polyps and adenomas and tend to grow extremely slowly. Colorectal carcinoma does not cause any distinct problems until it is in an advanced stage. In its early stage, however, there are only very non-specific symptoms: altered bowel habits such as more frequent bowel movements and constipation, stool that is different in appearance, smell or consistency, pain during bowel movements, or digestive problems, such as bloating or loud abdominal sounds. The earlier colorectal carcinoma is discovered, the better the chance that it can be cured (see stages on the next page).

The gold standard of colorectal cancer screening is the 'high' colonoscopy where the entire large intestine and the last section of the small intestine can be examined with an endoscope. Individuals covered by statutory health insurance are eligible for a screening colonoscopy starting at the age of 50

in some countries, 55 in others. During the colonoscopy, potential colon polyps that otherwise might develop into potentially malignant tumours can be removed right away. If the results are negative, the patient is eligible for another screening colonoscopy after ten years. This allows a physician to detect polyps and adenomas very reliably, resulting in the almost 100 per cent prevention of colorectal cancer if regular colorectal cancer screenings are performed.

However, patients' acceptance of this screening procedure is not particularly high: on average, only about 23 per cent of those eligible take advantage of the availability of screening colonoscopies. Many people shy away from the required bowel cleansing and the risk of infection, bowel perforation or bleeding during the procedure.

While colonoscopy is the most reliable method for detecting colorectal cancer in its early stages, it is also a costly procedure and uncomfortable for the patient. Immunological tests for faecal occult blood (FIT) are less of a burden and reliable at the same time. Tests for faecal occult blood that might originate in colon tumours or polyps are clearly less of a burden for the patient. In the majority of European countries, individuals between the ages of 50-74 are eligible to participate for free in the different screening programmes. The early detection cancer directives differ slightly from country to country around Europe. Some countries organise CRC screening programmes on a national or regional level, and the eligible population is formally invited to participate. In other European countries, screening is still opportunistic and offered by accredited GPs and paid for by statutory health insurance schemes. The stool test is not a replacement for colonoscopy. However, it can be a simple means of detecting tumours.

#### IMMUNOLOGICAL TEST IS BECOMING A ROUTINE PROCEDURE

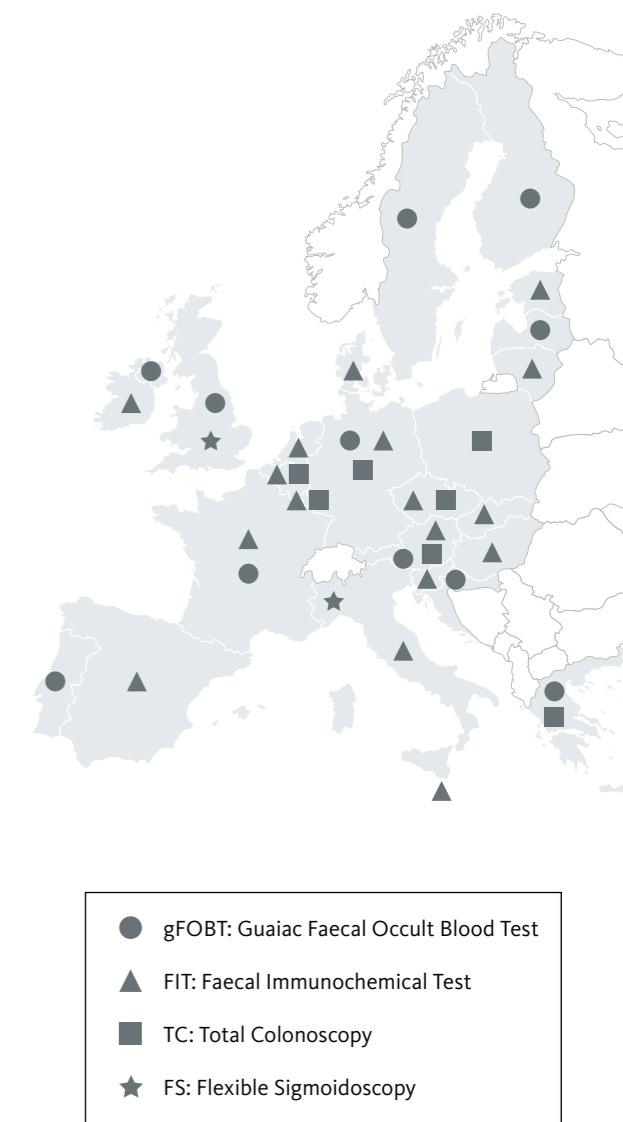
Some laboratories are still using chemical qualitative occult blood tests. The best-known is the gFOB (guaiac). To perform this qualitative test, there is a need to apply two samples each of three consecutive bowel movements to a small card. Certain foods, drugs or even menstrual bleeding can falsify the test result as it is not specific to human haemoglobin. An immunological test for faecal occult blood clearly delivers more reliable results. The test contains specific antibodies that bind to the substance in the sample. Patients only have to collect the stool sample with a sample collector and introduce the collector device inside a tube. After placing the test tube in the analyser without any further manipulation, drops of the fluid are applied to a test cassette where an immunological reaction takes place within a few minutes that searches for traces of haemoglobin. The test responds exclusively to human haemoglobin and is therefore not affected by the food the patient has eaten.

The FIT solutions offered by Sysmex, which combined the automated analysers with the Sentifit pierce tube and FOBGold Latex, allow the quantification of the human haemoglobin in the stool. According to the studies the concentration of the haemoglobin in the stools is a good first indicator of the severity of the lesions. The WEO expert group intends to standardise reimbursed immunological tests and to conduct them using quality-based methods in a laboratory via au- ▶

## CRC SCREENING IN EU MEMBER STATES

Organised or opportunistic: the efficiency of colorectal cancer screening programmes has led to their implementation in the health policies of all EU member states.

Nearly every EU state has its own screening based on FS (Flexible Sigmoidoscopy), TC (Total Colonoscopy) gFOB (Guaiac Faecal Occult Blood Test) or, and increasingly more often, FIT (Faecal Immunochemical Test). Some countries are currently running pilot assessment phases for FIT. This is an overview of the tests used in 2016:



Source: European Commission: Against Cancer. Cancer Screening in the European Union (2017), [https://ec.europa.eu/health/sites/health/files/major\\_chronic\\_diseases/docs/2017\\_cancerscreening\\_2ndreportimplementation\\_en.pdf](https://ec.europa.eu/health/sites/health/files/major_chronic_diseases/docs/2017_cancerscreening_2ndreportimplementation_en.pdf)

## STAGES OF COLORECTAL CANCER

The earlier it is detected, the higher the chance that it will be cured

### Stage 0 (Tis, N0, M0)

The tumour is still extremely small and only located in the upper layers of the intestinal mucosa. It is generally detected during a colonoscopy when polyps are removed and then analysed in the lab. There are no symptoms in Stage 0. If the necessary surgical procedure is conducted expertly, the chance of being cured is excellent.

### Stage I (T1 – 2, N0, M0)

There is also a very good chance of being cured from this early form of colorectal cancer. The lymph nodes have not been affected and after expert surgical removal of the tumour, there is no risk of metastasis. Chemotherapy or radiation therapy are not required. Even at stage I, a tumour causes no remarkable symptoms and is therefore only detected as part of colorectal cancer screening.

### Stage II (T3 – 4, N0, M0)

The tumour is limited to the intestinal wall. However, it has already penetrated all of its layers. The lymph nodes are not yet affected and there are no metastases yet. The five-year survival rate in patients with Stage II colorectal cancer is 85%. With Stage II rectal cancer, a combined radiation and chemotherapy is recommended in addition to surgery. With stage II colorectal cancer, however, this is not the case.

### Stage III (T1 – 4, N1 – 2, M0)

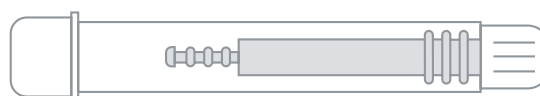
Advanced colorectal cancer cannot always be completely and permanently removed by surgery. At this stage, too, the tumour is initially surgically removed. With colorectal cancer, chemotherapy is also necessary; with rectal cancer, combined radiation and chemotherapy is required. The five-year survival rate in patients with Stage III is about 53%.

### Stage IV (T1 – 4, N0 – 2, M1)

Very advanced colorectal cancer has already formed metastases in other organs. Some of these can already be removed during the surgical removal of the colorectal cancer. Other tumours are initially reduced by chemotherapy and are then removed during a later, second surgery. A cure is only rarely possible. However, thanks to new chemotherapy drugs, quality of life and survival rate have significantly improved during the past few years.

tomated procedures. Some countries have already implemented reimbursement for FIT testing while other countries are still working on it.

In the Netherlands, the FIT is been used successfully since 2014. According to Wolfert Spijker, a central, uniform organisation, support by regional, regional and local institutions and a comprehensive database are the framework conditions which led to the success of screenings in the Netherlands: 'We have a central database into which all the invitations and results are entered. There we can evaluate the screening program in a very short-cycle, which is perfect.' One of the main advantages of FIT tests is their extremely uncomplicated application. By this, the inhibition threshold for participating in the screening is lowered. Also, the fact that all people have to do is simply put the test in an envelope and throw it into the nearest letterbox explains the active participation. In addition to economic reasons – compared to the colonoscopy it is quite inexpensive – its reliability is also convincing: 'The FIT test has a major advantage as it is quantitative so that no interpretation from the doctor is required. Another benefit is that you can carry out high-volume testing because the throughput is fast: you can easily analyse a few thousand tests per day.'



Patented Universal Collection tube offers flexibility and scalability for all lab requirements

Sources:

- 1 United European Gastroenterology [www.ueg.eu](http://www.ueg.eu)
- 2 Cancer Screening in the European Union (2017), Report on the implementation of the Council, Recommendation on cancer screening

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