

## PROTOCOL FOR COLORECTAL CANCER SCREENING

### **Recommendation of the expert group set up by the National Cancer Screening Steering Group**

The recommendation is based on the European Union Recommendation on cancer screening (1) and on studies conducted in Finland and elsewhere in Europe (2-5).

The primary screening method is the immunochemical faecal blood test (FIT), for which separate guidance from the expert group is provided in this document. Men and women aged 56-74 years are invited for screening every two years (6). Screening will be progressively extended to this age group between 2022 and 2031 (Figure 1).

Two reminders will be sent to non-participants.

If no blood is found in the stool sample of a screened participant when analysed, the next screening invitation will be sent after two years. If blood is then found in the stool sample, the individual is advised to contact the screening nurse. The screening nurse performs assessment for further examination.

The majority of people who test positive will, after assessment, proceed to further examination, primarily colonoscopy. If the finding at follow-up is non-neoplastic, the individual will be next invited for screening after six years (7). A neoplastic finding is treated and followed up according to standard practice in specialist care and the next invitation to screening will be after ten years (8).

People with inflammatory bowel disease (IBD), who have had their colon removed (colectomy) or who are being followed up due to colorectal cancer will not be referred for further examination. Diagnoses and follow-up are verified in the medical records of patients in specialist care.

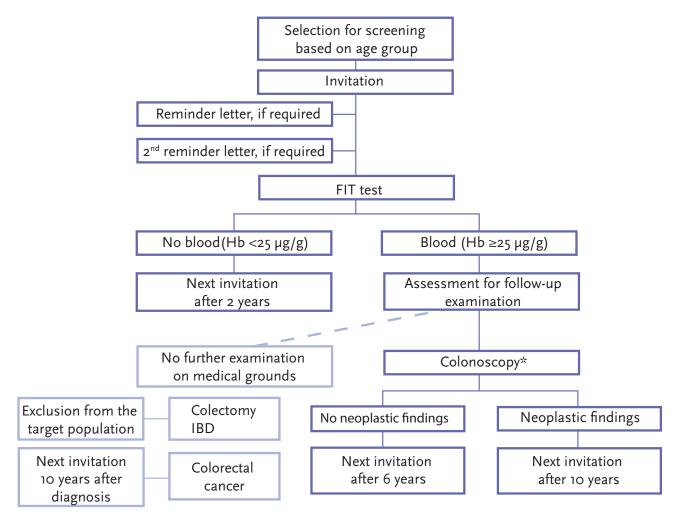
Patients with IBD and colectomy will not receive a new screening invitation. Those who are being followed up due to colorectal cancer will be invited for screening ten years after diagnosis (8).

# Figure 1. Screening expansion

	Calendar y	ear								
Year of birth	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031
1975	47	48	49	50	51	52	53	54	55	56
1974	48	49	50	51	52	53	54	55	56	57
1973	49	50	51	52	53	54	55	56	57	58
1972	50	51	52	53	54	55	56	57	58	59
1971	51	52	53	54	55	56	57	58	59	60
1970	52	53	54	55	56	57	58	59	60	61
1969	53	54	55	56	57	58	59	60	61	62
1968	54	55	56	57	58	59	60	61	62	63
1967	55	56	57	58	59	60	61	62	63	64
1966	56	57	58	59	60	61	62	63	64	65
1965	57	58	59	60	61	62	63	64	65	66
1964	58	59	60	61	62	63	64	65	66	67
1963	59	60	61	62	63	64	65	66	67	68
1962	60	61	62	63	64	65	66	67	68	69
1961	61	62	63	64	65	66	67	68	69	70
1960	62	63	64	65	66	67	68	69	70	71
1959	63	64	65	66	67	68	69	70	71	72
1958	64	65	66	67	68	69	70	71	72	73
1957	65	66	67	68	69	70	71	72	73	74
1956	66	67	68	69	70	71	72	73	74	75
1955	67	68	69	70	71	72	73	74	75	76
1954	68	69	70	71	72	73	74	75	76	77
1953	69	70	71	72	73	74	75	76	77	78

Age

### Screening protocol



\*or CT colonography

## **TESTS USED IN SCREENING**

The primary screening method is the faecal immunochemical blood test (FIT), which has been validated and used in European screening programmes over several rounds of screening (9-11).

The tests should be quantitative, with an automatically adjustable sensitivity level.

The sensitivity level of the screening programme is based on research evidence and is set at the threshold of  $25 \mu g$  Hb/g of faeces for both sexes in 2022 (5,12,13). The impact of the sensitivity level on screening performance and outcomes will be monitored by the Finnish Cancer Registry. The cut-off value will be updated based on the proportion of positives, the need for colonoscopy and the accumulation of research data.

Test preservation and adequate intra-laboratory and inter-laboratory transfer of test results should be ascertained by regular monitoring by screening laboratories (14).

Using these criteria, the FIT tests listed below have been validated for screening use in men and women aged 56-74 years:

- FOB Gold NG, Sentinel CH. SpA, Italy
- OC-Sensor Diana, Eiken Chemical Co. Ltd, Japan
- OC-Sensor Pledia, Eiken Chemical Co. Ltd, Japan

The list has been updated on 21.9.2021. The list will be updated by the expert group in the future as research data becomes available.

#### **Further information**

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## **References:**

1. Council recommendation of 2. December 2003 on cancer screening (2003/878/EC). Off J Eur Union 2003; (L327): 34-8.

2. Lauby-Secretan B, Vilahur N, Bianchini F ym. IARC Handbook Working Group. The IARC perspective on colorectal cancer screening. NEJM 2018; 378: 1734-40.

3. Sarkeala T, Färkkilä M, Anttila A ym. Piloting gender-oriented colorectal cancer screening with a faecal immunochemical test: population-based registry study from Finland. BMJ Open 2021; 11: e046667.

4. Wieten E, Schreuders EH, Grobbee EJ ym. Incidence of faecal occult blood test interval cancers in population-based colorectal cancer screening: a systematic review and meta-analysis. Gut 2019; 68: 873-81.

5. Heinävaara S, Gini A, Sarkeala T ym. Optimizing screening with faecal immunochemical test for both sexes – cost-effectiveness analysis from Finland. Submitted.

6. Government Decree amending Article 2 of the Government Decree on Screening (752/2021)

7. Murthy SK, Dube C, Rostom A ym. Risk of colorectal cancer after a negative colonoscopy in low-tomoderate risk individuals: impact of a 10-year colonoscopy. Endoscopy 2017; 49: 1229-36.

8. European Society of Gastrointestinal Endoscopy (ESGE) Guideline. Endoscopy 2013; 45:842-51.

9. Crotta S, Segnan N, Paganin S ym. High rate of advanced adenoma detection in 4 rounds of colorectal cancer screening with the fecal immunochemical test. Clin Gastroenterol Hepatol 2012; 10: 633-38.

10. Portillo I, Arana-Arri E, Idigoras I ym. Colorectal and interval cancers of the colorectal cancer screening program in the Basque country (Spain). World J Gastroenterol 2017; 23(15): 2731-42.

11. Toes-Zoutendijk E, Kooyker AI, Dekker E ym. Incidence of interval colorectal cancer after negative results from first-round fecal immunochemical screening tests, by cutoff value and participant sex and age. Clin Gastroenterol Hepatol 2020; 18(7):1493-500.

12. Grobbee EJ, van der Flugt M, van Vuuren AJ ym. A randomised comparison of two immunochemical tests in population-based colorectal cancer screening. Gut 2017; 66: 1975-82.

13. de Klerk C, Wieten E, Landsdorph-Vogelaar I ym. Performance of two immunochemical tests for the detection of advanced neoplasia at different positivity thresholds: a cross-sectional study of the Dutch national colorectal cancer screening program. Lancet Gastroenterol Heptol 2019; 4: 111-18.

14. Gies A, Cuk K, Schrotz-King P, Brenner H. Direct comparison of ten quantitative fecal immunochemical tests for hemoglobin stability in colorectal cancer screening. Clinical and Translational Gastroenterologt 2018; 9: 168.

## Composition of the expert group

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