



# Quantitative FIT tests in the Czech Republic Past, present and future

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Laboratory of Gastroenterology of the  
Institute of Medical Biochemistry and Laboratory Diagnostics  
shows long-standing – 40 years experiences with FOBT analytics

## 1st GENERATION OF FOBT GUAIAC TEST: g-FOBT

1970 – 1980 different chemically based tests with guaiac or o-tolidine were compared for reproducibility, sensitivity and assurance

**Haemoccult, HemDetect, KryptoHaem SSW**

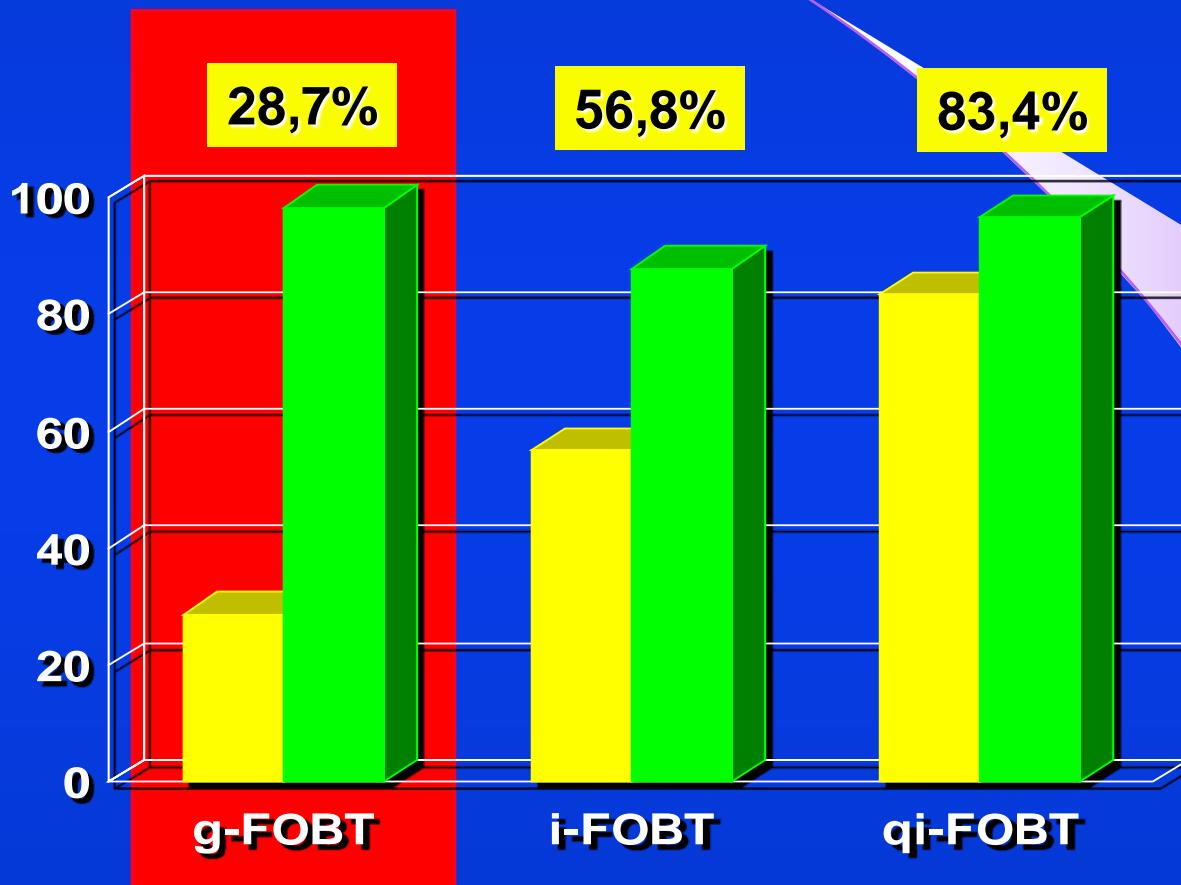


Haemoccult exclusively has been recommended for CRC screening with highest reproducibility

*An adapted program of colorectal cancer screening.*  
**Fric P, Zavoral M, Dvoráková H et al. - Hepatogastroenterology. 1994**



## g-FOBT – GUAJAC TEST, HAEMOCCULT



g-FOBT WITH SENSITIVITY LESS 30% FINISHED AT END OF 2012



## i-FOBT QUALITATIVE, RAPID TESTS

**1990 – 2000** different immunochemically tests were compared for reproducibility, sensitivity and assurance, compared with Haemoccult, and validated by colonoscopy.

**ImmoCare, HemeSelect, Hemolex, Actim FB, Hexagon OBTI**



**None of iFOBT test has been recommended for CRCA screening.**  
iFOBT tests are very different in sensitivity, very high false positivity - more than 25%, and variable sample preparation

*Ferkl M, Kocna P, Fric P. - Cas Lek Cesk. 1992*

*Benesova A, Fric P, Zavoral M, Kocna P, et al. - Cas Lek Cesk. 1993*

*Dvorak M., Kocna P. Vanickova Z. - Cas Lek Cesk. 2002*

*Dvorak M., Kocna P. et al. - Z.- Facharzt. 2003*



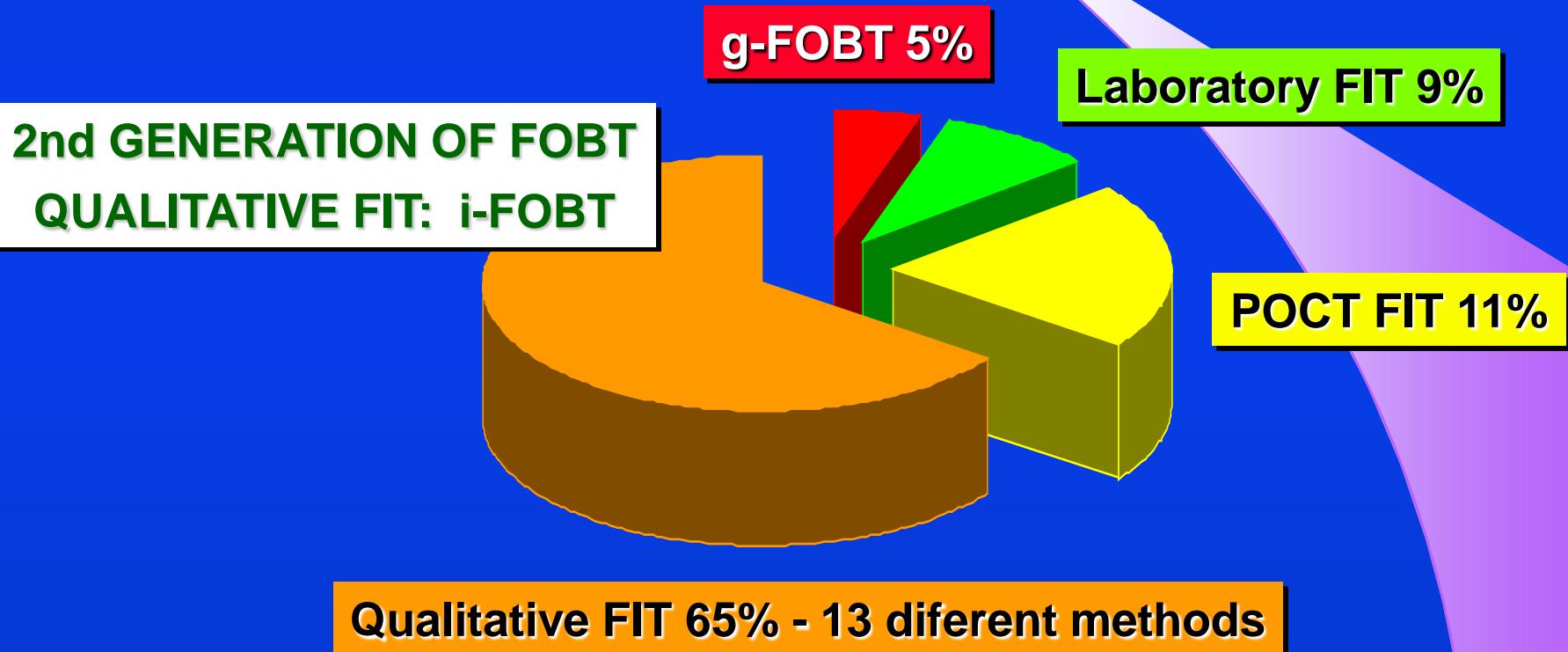
## FOBT - THE PAST

20 YEARS WE USED g-FOBT  
WITH LOW SENSITIVITY  
BUT THE SAME RELIABILITY IN ALL  
REGIONS OF THE CZECH REPUBLIC



## i-FOBT methods for screening in the Czech Republic in 2013

### SURVEY IN GENERAL PRACTITIONERS IN 2014





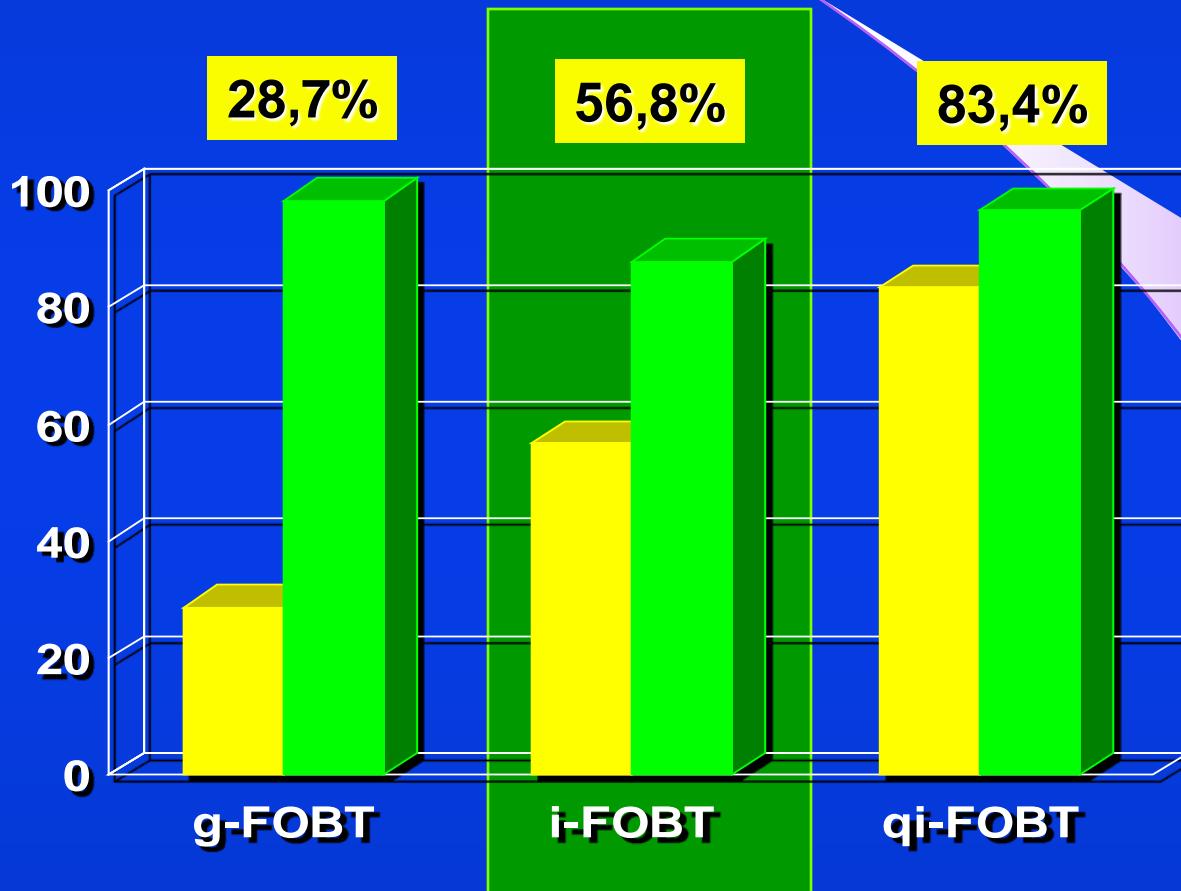
## i-FOBT QUALITATIVE, RAPID TESTS



HIGH RANGE of iFOBT RAPID TESTS  
AVAILABLE NOW IN THE CZECH REPUBLIC



## i-FOBT QUALITATIVE, RAPID TESTs



i-FOBT SENSITIVITY COULD BE 2x HIGHER AS HAEMOCCULT



## i-FOBT QUALITATIVE, RAPID TESTS

- ✓ iFOBT Rapid tests available in the CR from 20 producers
- ✓ iFOBT tests varied highly in the sensitivity and accuracy
- ✓ iFOBT tests sensitivity varied from 100 ng Hb/ml to 2000 ng Hb/ml
- ✓ Rapid iFOBT tests use very different sampling devices
- ✓ Rapid iFOBT tests varied in the Hb/extract buffer stability

Haug U, Hundt S, Brenner H. - Am J Gastroenterol. 2010 Mar;105(3):682-690

*Quantitative immunochemical fecal occult blood testing for colorectal adenoma detection: evaluation in the target population of screening and comparison with qualitative tests.*

- ✓ Mayo Clinic study of 750 subjects, colonoscopy verified
- ✓ FIT qualitative - false positivity - 7.4%
- ✓ FIT quantitative - false positivity - 3.8%

*Colorectal Cancer Screening Committee, DDW 2012 Workshop  
Expert Working Group – Fit for Screening - prof. Stephen Halloran  
Director: NHS Bowel Cancer Screening*



## UNITS & CUT-OFF VALUE (ng Hb/ml / $\text{mg}$ Hb/g stool)

FIT test	Sampling	Conc.	Ratio	cut-off	cut-off
		mg/ml		ng/ml	$\text{mg}/\text{g}$
ColonView	1mg/2ml	0.50	1	40	80
immo-Care-C	11.5 mg/2.5ml	4.60	9,2	50	11
FOB Test	10mg/2ml	5.00	10	40	8
OC-Light	10mg/2ml	5.00	10	50	10
EpiTuub® iFOB	5-10mg/1.1ml	4,5-9	9-18	50	5.5-11
Hema-screen™	x / 1.7-1.8ml	1.00	2	50	50
FOB test	3-10mg/3ml	1.0-3,3	2-6,6	10	3.3-10
Hb FECALE	100-200mg/2ml	50-100	100-200	40	0.4-0.8
Actim Fecal Blood	10-20mg/10ml	1.0-2.0	2-4	50	25-50
Easy-Card				200	
SureScreen FOB				50	

Tests with **identical** cut-off in Hb ng/ml  
may have up to **200x times higher, or lower**, cut-off in  $\text{mg}$  Hb/g stool



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IN 2013 WE CHANGED TO i-FOBT (FIT)  
WITH 2-TIMES HIGHER SENSITIVITY  
BUT DISTINCTLY INCREASING VARIABILITY  
IN REGIONS OF THE CZECH REPUBLIC

## QUANTITATIVE Hb ANALYSIS IN STOOL

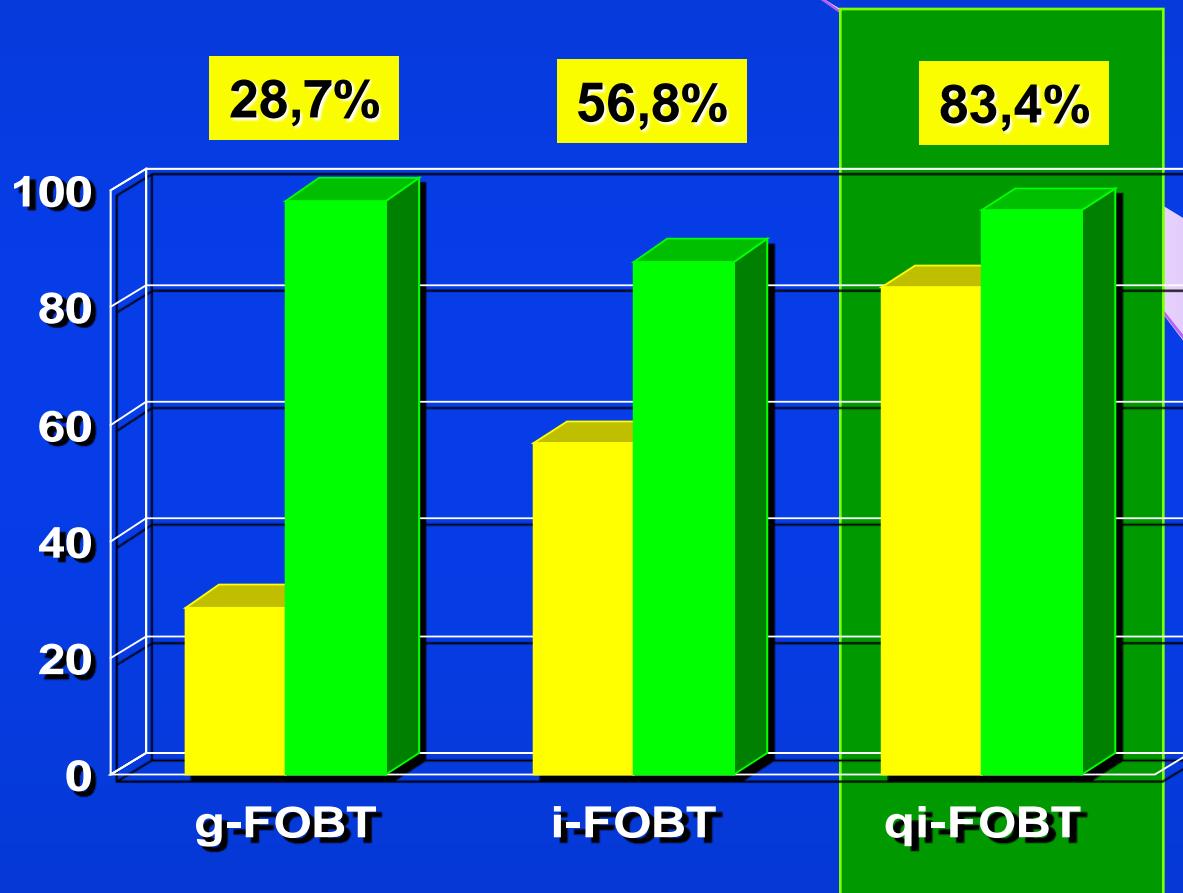
- ✓ Qualitative, rapid tests, quantified by the scanner/software
- ✓ POCT analysers at general practitioners
- ✓ Chemical/biochemical analysers at hospital/laboratories

**3rd GENERATION OF FOBT  
QUANTITATIVE FIT: qi-FOBT**

**Started 5 years ago**



## qi-FOBT/FIT - QUANTITATIVE Hb ANALYSIS IN STOOL



qi-FOBT SENSITIVITY COULD BE 3x HIGHER AS HAEMOCCULT

## RAPID iFOBT QUALITATIVE TEST



STANDARD PC - SCANNER

PC - NOTEBOOK



EVALUATION OF COLOURED BAND INTENSITY  
COMPARING WITH DIGITAL / COLOUR STANDARD  
QUANTIFICATION OF iFOBT TEST = ONLY PC'S VISUALISATION

## qi-FOBT / FIT POCT & LABORATORY ANALYSERS

OC-Sensor Eiken



QuikRead Orion



OC-DIANA Eiken



i-Chroma Boditech



QuikReadGo Orion

SmartPlus Eurolyser



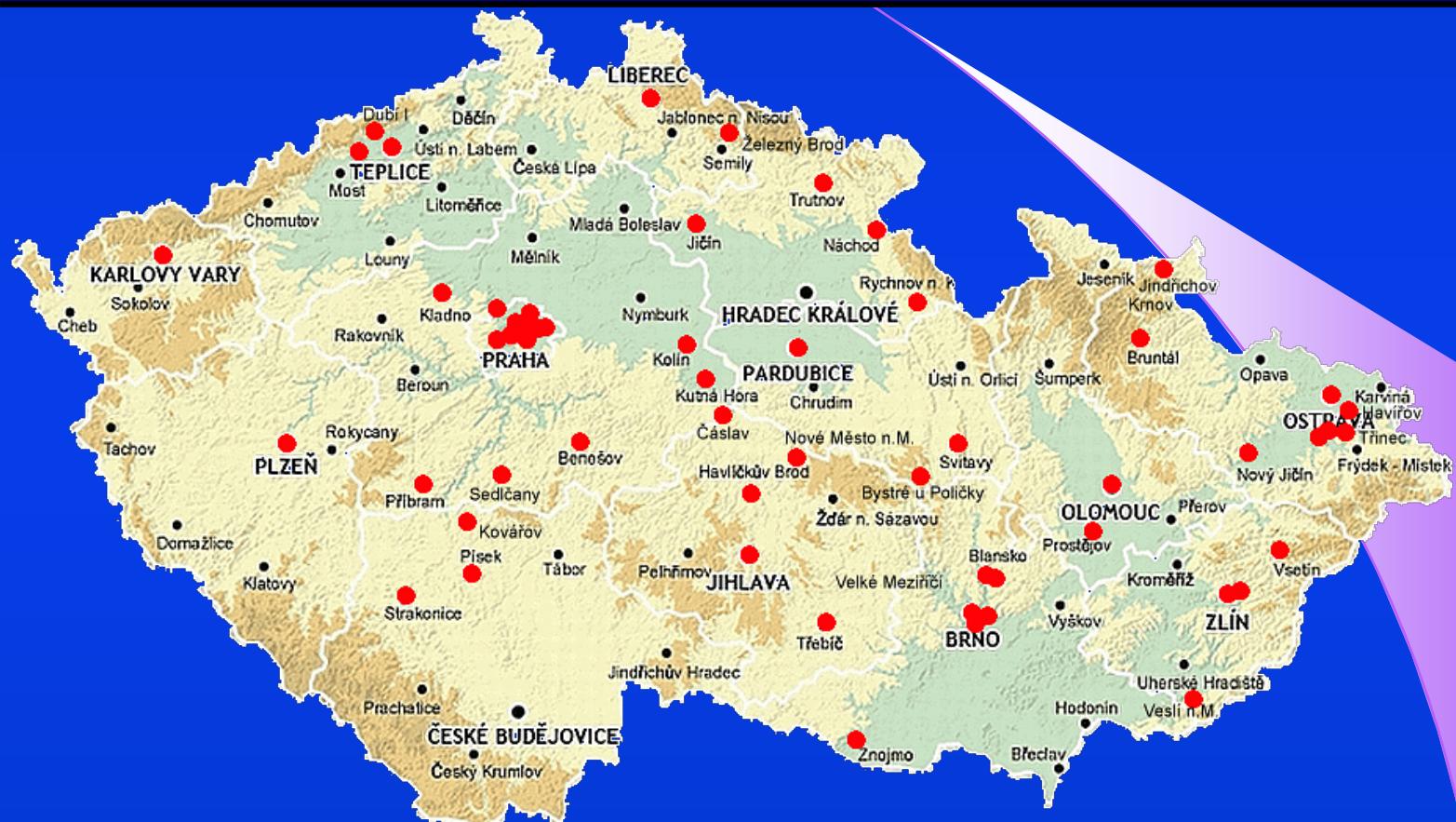
SENTi-FIT 270 Sentinel



SENTi-FIT mini Sentinel



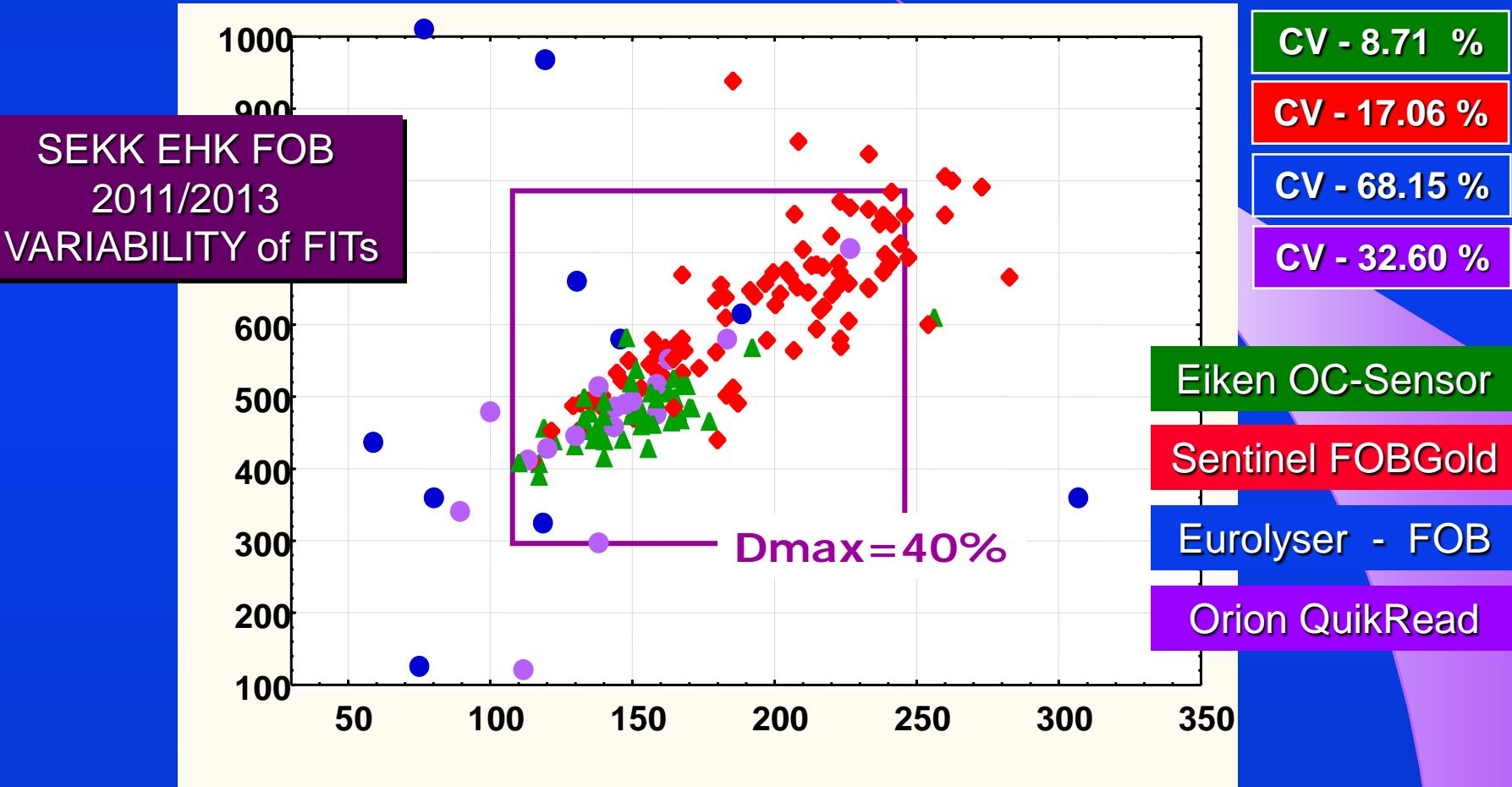
## QUANTITATIVE FIT ANALYSERS IN CZECH REPUBLIC



Map of the Czech Republic with marked locations

where the quantitative analysis of Hb in stool,  
controlled with the SEKK external control quality, is available

## EXTERNAL CONTROL QUALITY SYSTEM in CR

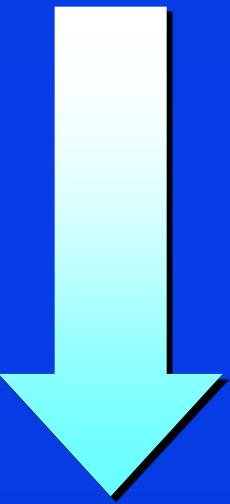


Kocna P., Zima T., Budina M., Ichiyangai T.: External Quality Assessment (EQA) for Quantitative Fecal Blood in Stool (FIT). Biochimica Clinica, 2013, 37, 423



Automated analysers for qFOBT are ready to start CRC screening  
with qFOBT optimised for Czech Republic screening  
EQAS control system is since January 2012 available

Committee for CRC screening  
Ministry of Health  
of the Czech Republic



National screening programme in the Czech Republic  
**should be modified to use quantitative qFOBT technology**

2 years ago

*Quantitative immunochemical qFOBT OC-Sensor  
Meeting with EC & EP – Prague, January 11, 2012*



## QUANTITATIVE Hb STOOL ANALYSIS IN PRAGUE

EXPERIENCES IN GENERAL FACULTY HOSPITAL - PRAGUE, 2008 - 2013



Quantitative determination of Hb in stool  
Eiken OC-Sensor micro analyser  
General Faculty Hospital Prague  
15 000 analysis in 5 years (2008 - 2013)  
The analytical data-mining tool I-COP  
(Cancer Care Information Centre) compare  
Laboratory data - FIT - Hb in stool  
with National Cancer Registry output



**Kocna P., Májek O., Blaha M.: Clinical and epidemiological importance of analyzing laboratory data with the data source I-COP.**  
**Sborník Medsoft 2014 - March 25; 110-122**  
**on-line: <http://creativeconnections.cz/medsoft/2014.html>**



## DETECTED COLORECTAL CANCERS

AGE 50 – 90 YEAR ( n = 4145 )

ng/ml	n	FIT +
75	292	7.05 %
> 1000	47	1.13 %

Patients of the Center for Preventive Care & GPs

AGE 50 – 90 YEAR ( n = 6561 )

ng/ml	n	FIT +
75	1287	19.62 %
> 1000	311	4.74 %

Patients specialized hospital clinics outpatient and inpatients

Detected CRC – 11/64

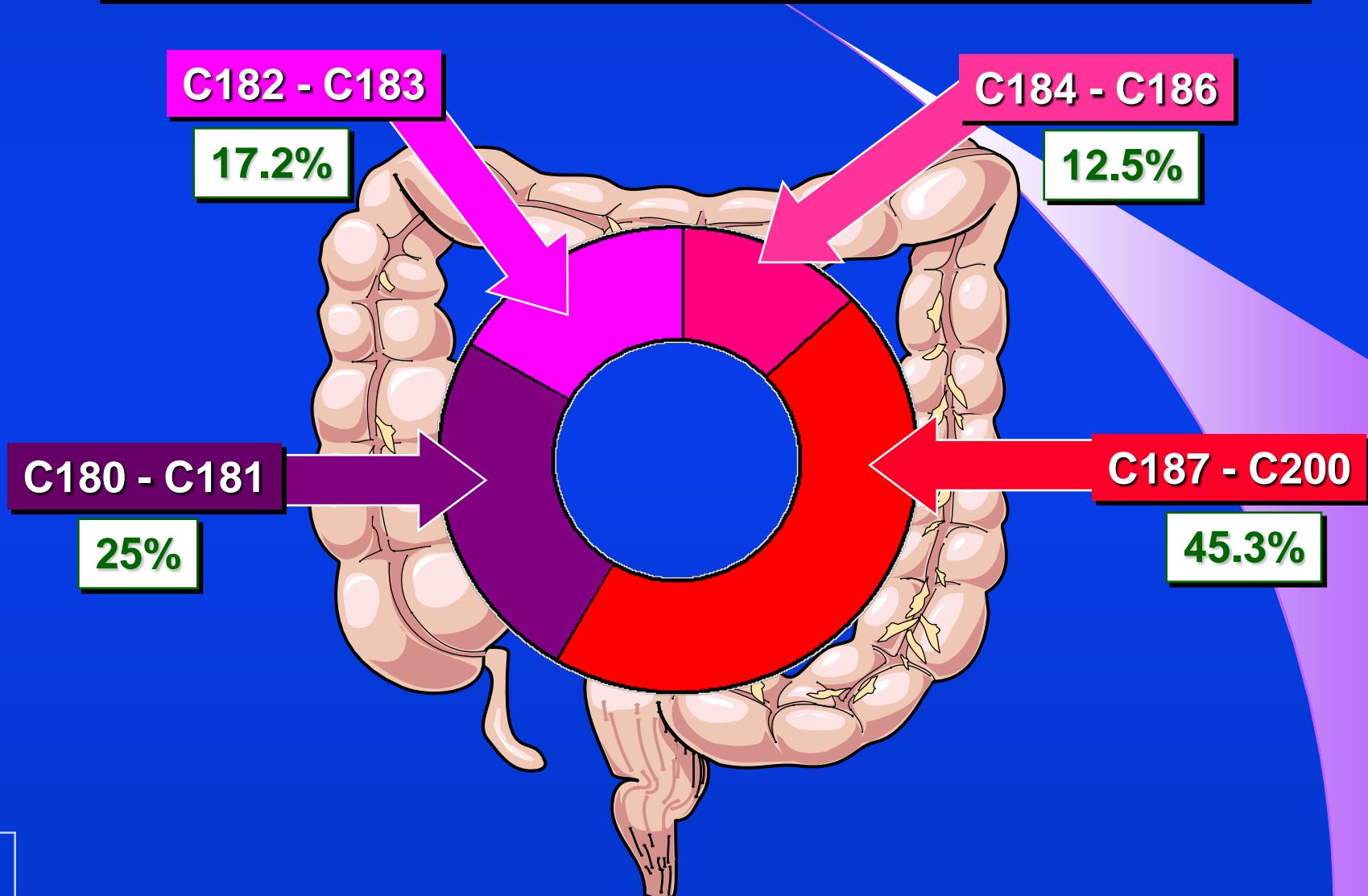
Detected CRC – 53/64

CRC detection rate - 2.65/1000 FIT  
Average time FIT - surgery: 5.34 months

CRC detection rate - 8.08/1000 FIT  
Average time FIT - surgery: 2.95 months

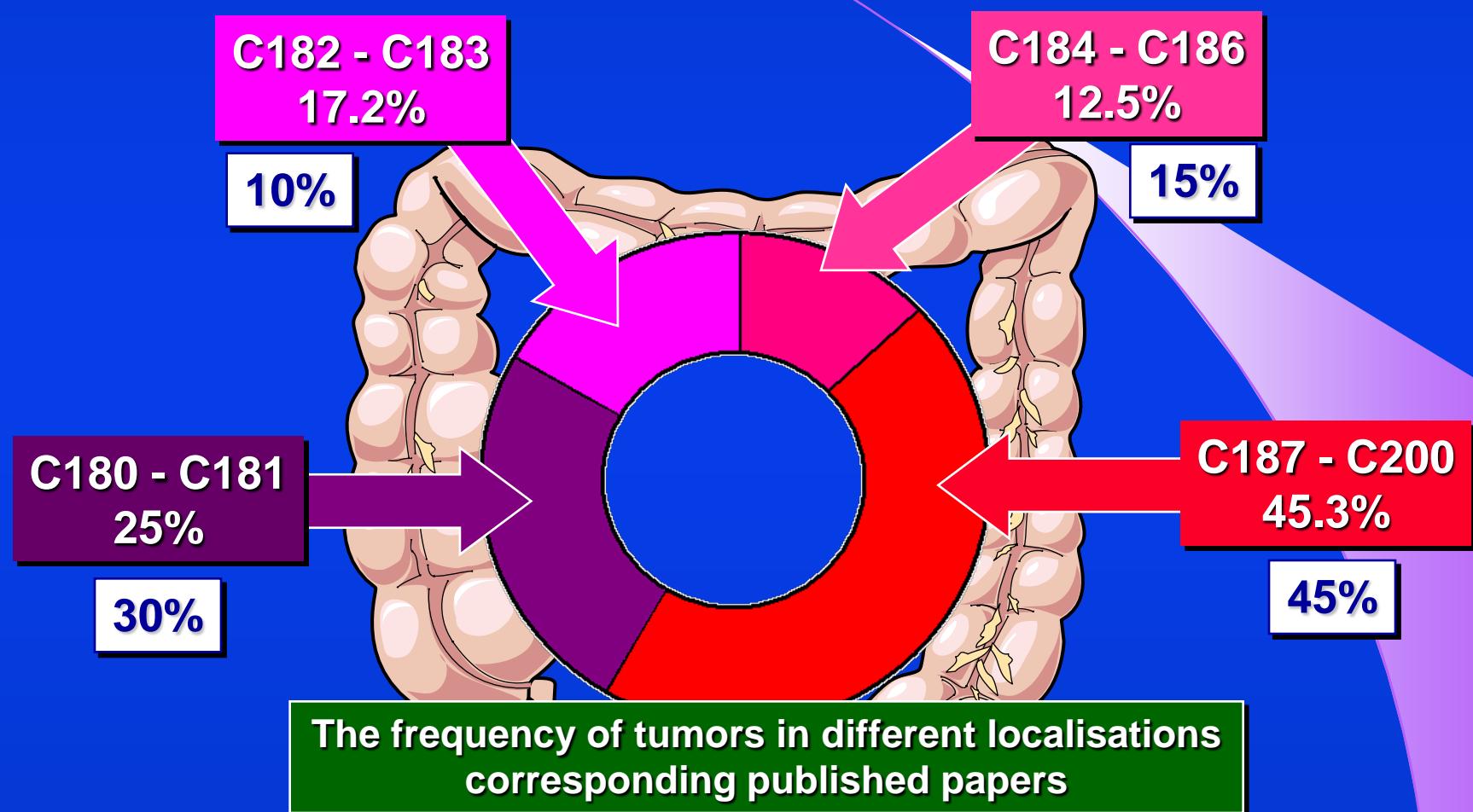


## CRC TUMOR - BOWEL LOCALISATION



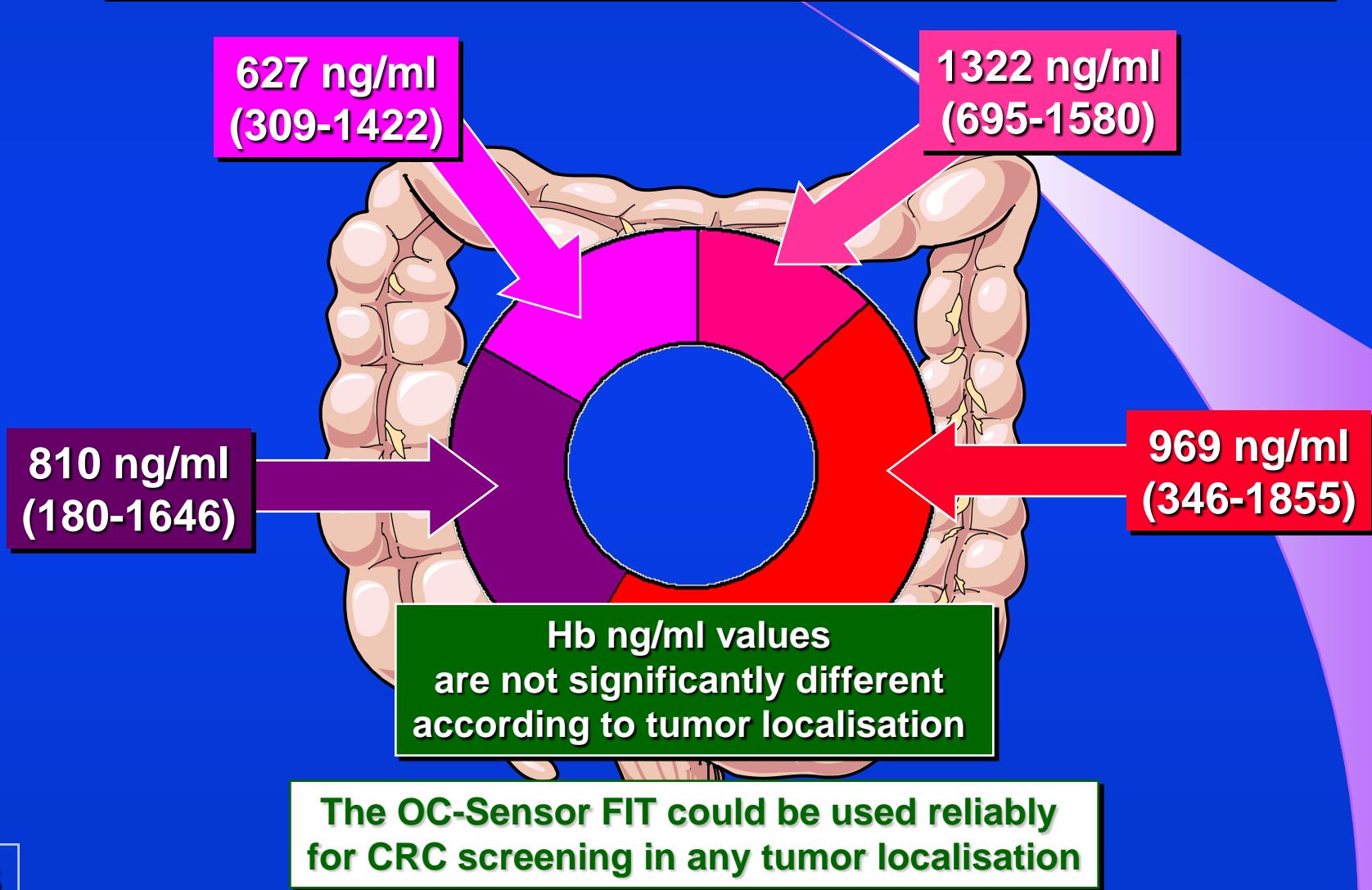


## CRC TUMOR - BOWEL LOCALISATION





## CRC TUMOR - BOWEL LOCALISATION & FIT VALUE





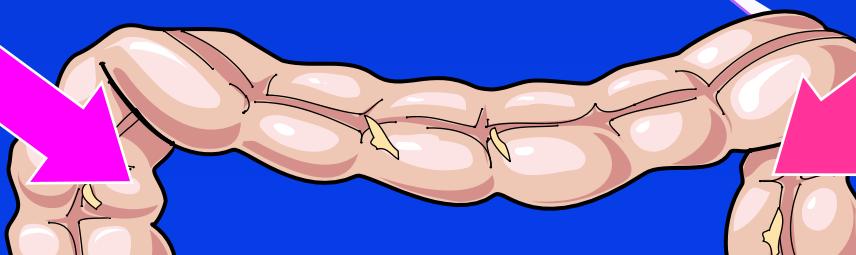
## OC - SENSOR FIT FALSE NEGATIVITY

1/11

9.1%

1/

12.5%



False negativity - is 15.62 %

(cut-off value 75 ng/ml recommended by the CRC Commission)

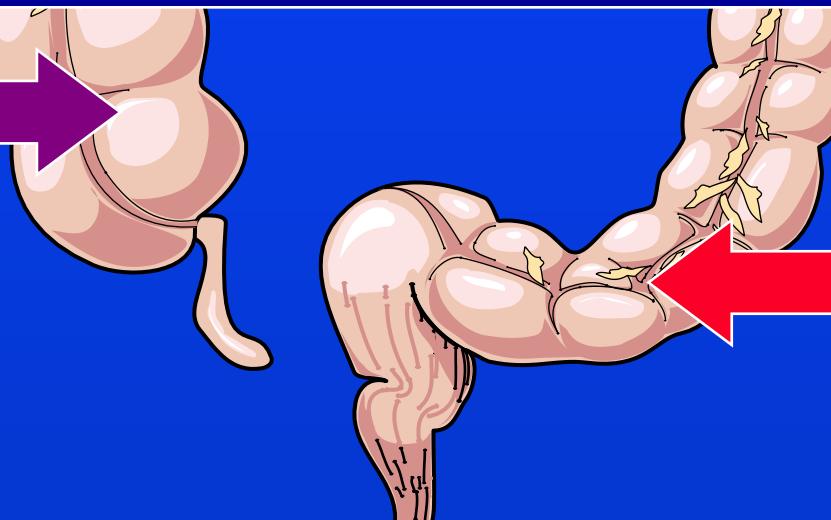
The sensitivity for CRC - is 84.38 %

3/16

18.7%

5/29

17.2%





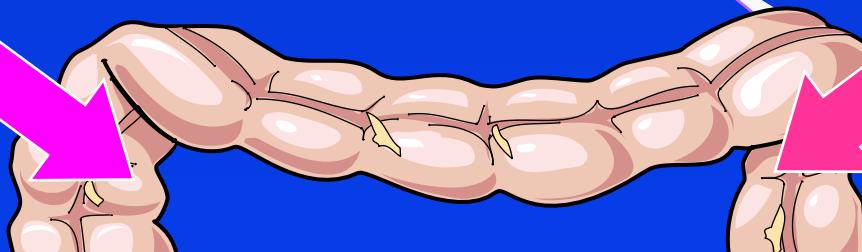
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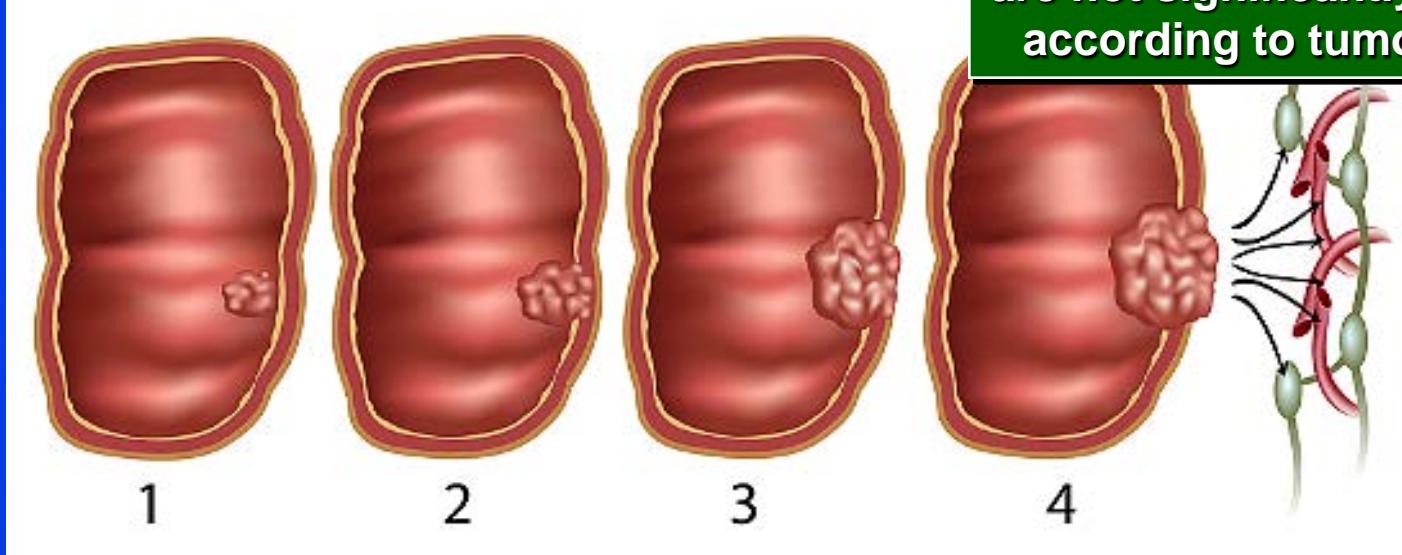
The percentage of unrecognized cancers - 17.6%  
for one test with cut-off 75 ng/ml



Kelley L, Swan N, Hughes DJ. - *Colorectal Dis.* 2013 Sep; 15(9): e512-21  
An analysis of the duplicate testing strategy of an Irish immunochemical FOBT colorectal cancer screening programme

## CRC TUMOR STAGE & FIT VALUE

Hb ng/ml values  
are not significantly different  
according to tumor stages



**CRC stage I**  
(n=11)  
1656 ng/ml  
(421-2154)

**CRC stage II**  
(n=21)  
960 ng/ml  
(453-1639)

**CRC stage III**  
(n=17)  
848 ng/ml  
(37-1554)

**CRC stage IV**  
(n=15)  
720 ng/ml  
(175-1396)



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## FOBT - THE FUTURE

PREMISE - VISIONS - SIX MAIN TASKS



## **FOBT - THE FUTURE**

### **PREMISE - VISIONS - SIX MAIN TASKS**

#### **1. TASK**

**ANALYSE THE EUROPEAN EXPERIENCES**



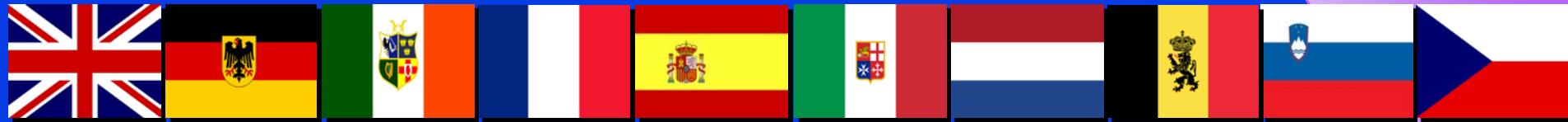
## EUROPEAN EXPERIENCES WITH FIT

We analysed 175 scientific publications, available on web

Publications focusing on CRC screening by FIT

Publications published in the last 5 years (2008-2013)

The presentation was focused only on studies of European countries



'EVIDENCE BASED' RECOMMENDATIONS  
AND EXPERIENCES ARE NOW AVAILABLE

Kocna P.: *The European experiences with FIT tests.*

Proceedings 2nd National Congress on Colorectal Cancer, Prague 2013, 359-369



## EUROPEAN EXPERIENCES WITH FIT

Recommendations for a colorectal cancer screening programme in Ireland - **12/2008**

**The National Cancer Screening Service Board, Ireland**

The Board's recommendation that the immunochemical faecal occult blood test (iFOBt) which operates on an **automated testing platform**.

Immunochemical faecal occult blood tests - Evaluation report - **November 2009**

**Centre for Evidence-based Purchasing of the NHS Purchasing and Supply Agency.**

**The OC-Sensor / DIANA analyser** is well designed and is the most suitable system for the **English bowel cancer screening programme**.

A national colorectal cancer screening programme, **November 17, 2009**

**The Health Council of the Netherlands**

The Committee recommends iFOBT-based screening (**OC-Sensor, one faecal sample**) once every two years for men and women between fifty-five and seventy-five years old.

Faecal occult blood test-based screening programme. **2009 May**

**Lecco Colorectal Cancer Screening Group**

Immunochemical faecal tests (**HM-Jack, Kiowa**; Japan) were processed by a single central laboratory using an **automated reading technique**; the positivity **cut-off was 100 ng/ml**.



## FOBT - THE FUTURE PREMISE - VISIONS - SIX MAIN TASKS

ANALYSE THE EUROPEAN EXPERIENCES

### 2. TASK

HIGHLIGHT QUANTITATIVE FIT



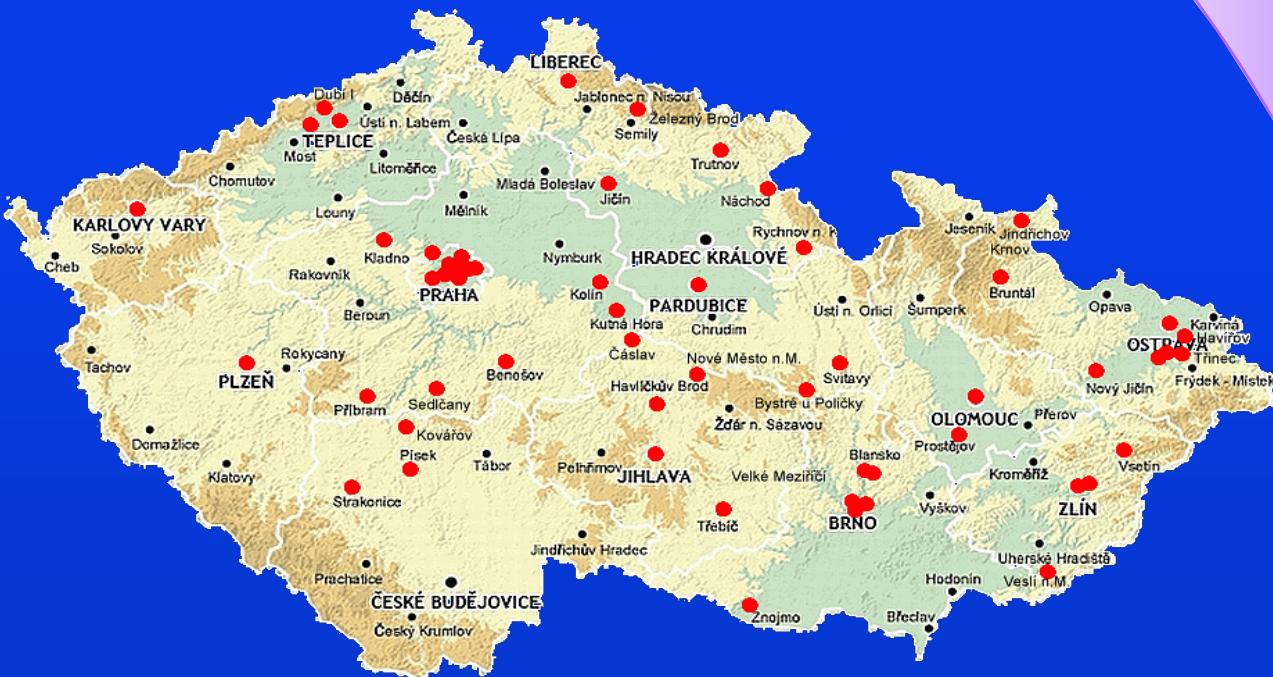
## HIGHLIGHT QUANTITATIVE FIT

- ✓ qFIT is 3 times more sensitive and reliable than gFOBT
- ✓ qFIT analysis is based on specific antibody technique
- ✓ qFIT on automatic analyzer eliminates subjective evaluation
- ✓ qFIT allows the quantitative analysis
- ✓ qFIT could be possible to optimize selecting screening cut-off
- ✓ qFIT allows comparing the values on a European scale
- ✓ qFIT may be monitor by quality control system EQAS



## HIGHLIGHT QUANTITATIVE FIT

At least 50 laboratories in the Czech Republic offers the quantitative determination of Hb in the stool, verified 2times per year by the external quality control system, with sufficient capacity for population screening of CRC.





## FOBT - THE FUTURE

PREMISE - VISIONS - SIX MAIN TASKS

ANALYSE THE EUROPEAN EXPERIENCES  
HIGHLIGHT QUANTITATIVE FIT

### 3. TASK

CLEARLY DEFINE CUT-OFF POSITIVITY



## Colorectal Disease - 09/2013

9704 kits (2 tests) sent out to residents, 50-74 years

return rate - 5023 (52%), positivity  $\geq$  100 ng/ml: 514 (10.2%)

419 FIT+ colonoscopy (81.5%) with caecal intubation 402 (96%)

CRC found 17 (4.1%), Dukes I + II in 62.5%, 132 advanced adenomas (31.5%)

	Positivity rate (95% CI)	Colonoscopies number	CRC & adv. adenomas	Specificity CRC & AA
FIT one	6.9% (6.3 - 7.7%)	287	108	96.4% (95.7 - 96.9%)
FIT two	10.2% (9.4 - 11%)	419	149	94.5% (93.7 – 95.1%)

### The percentage of unrecognized cancers

23.5% for one test with cut-off 100 ng/ml and 17.6% with 75 ng/ml neoplasms, including advanced adenomas - 32% (100 ng/ml) a 30% (75 ng/ml)

Kelley L, Swan N, Hughes DJ. - *Colorectal Dis.* 2013 Sep; 15(9): e512-21  
*An analysis of the duplicate testing strategy of an Irish immunochemical FOBT colorectal cancer screening programme*



## Biomedical Papers - 06/2012

**FIT test before colonoscopy - 815 people, two centers (VFN and  
Comparison of a two-FIT tests and different cut-off values  
FIT test - OC-Sensor micro**

Hb cut off - ng/ml	50	75	100	125	150
Sensitivity CRC - FIT 1	88.6% (73.2 - 96.7)	85.7% (69.7 - 95.1)	85.7% (69.7 - 95.1)	80.0% (63.1 - 91.5)	80.0% (63.1 - 91.5)
Sensitivity CRC - FIT 2	88.6% (73.2 - 96.7)	85.7% (69.7 - 95.1)	85.7% (69.7 - 95.1)	85.7% (69.7 - 95.1)	85.7% (69.7 - 95.1)
Specificity CRC - FIT 1	87.2% (83.6 - 90.2)	90.1% (86.8 - 92.8)	91.0% (87.9 - 93.6)	93.0% (90.1 - 95.2)	93.5% (90.6 - 95.6)
Specificity CRC - FIT 2	81.4% (77.3 - 85.0)	84.7% (80.9 - 88.1)	86.9% (83.3 - 90.0)	89.1% (85.7 - 91.9)	90.1% (86.8 - 92.8)

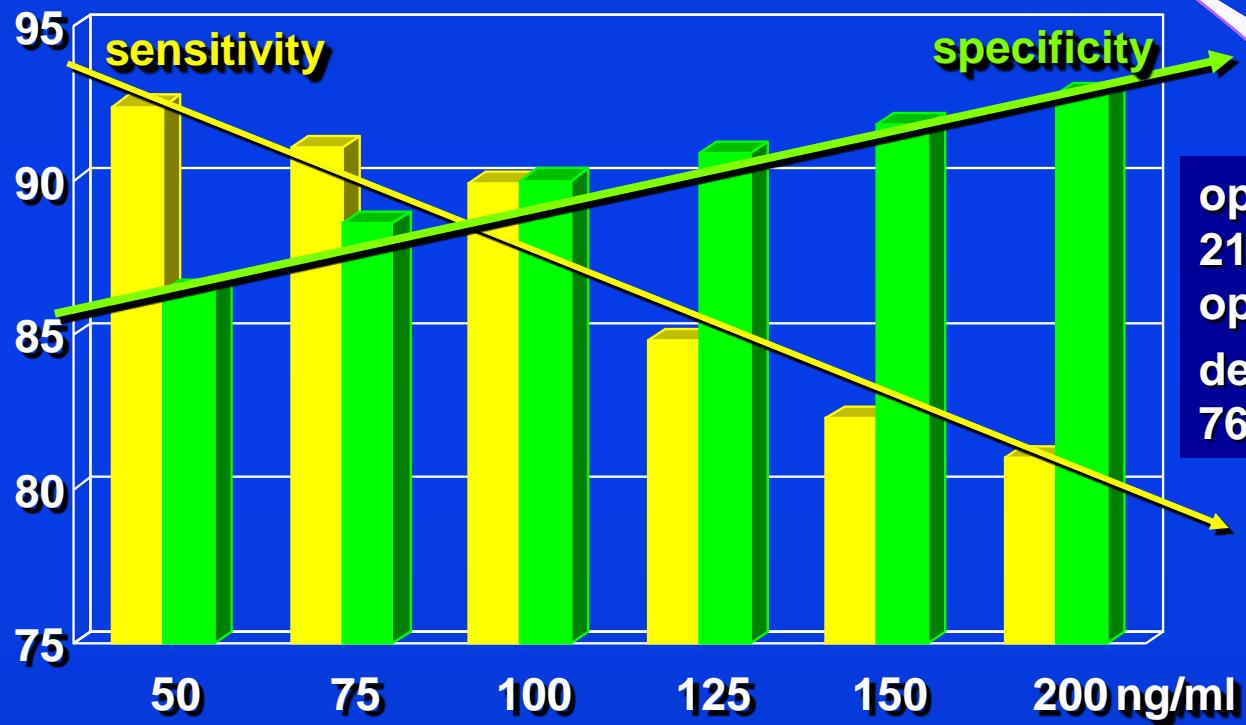
**Recommendation of Czech pilot study - one FIT test with cut-off value 75 ng/ml**

*Kovarova JT, Zavoral M, Zima T, Zak A, Kocna P. et al.*

*Biomed Pap 2012 Jun; 156(2): 143 - 150: Improvements in*

*colorectal cancer screening programmes - quantitative immunochemical faecal occult blood testing - how to set the cut-off for a particular population.*

## Cancer Epidemiol Biomarkers Prev - 2011



**optimization FIT cut-off**  
**2145 persons > 40 years**  
**optimization of screening**  
**define the minimum age**  
**76 CRC found by colonoscopy**

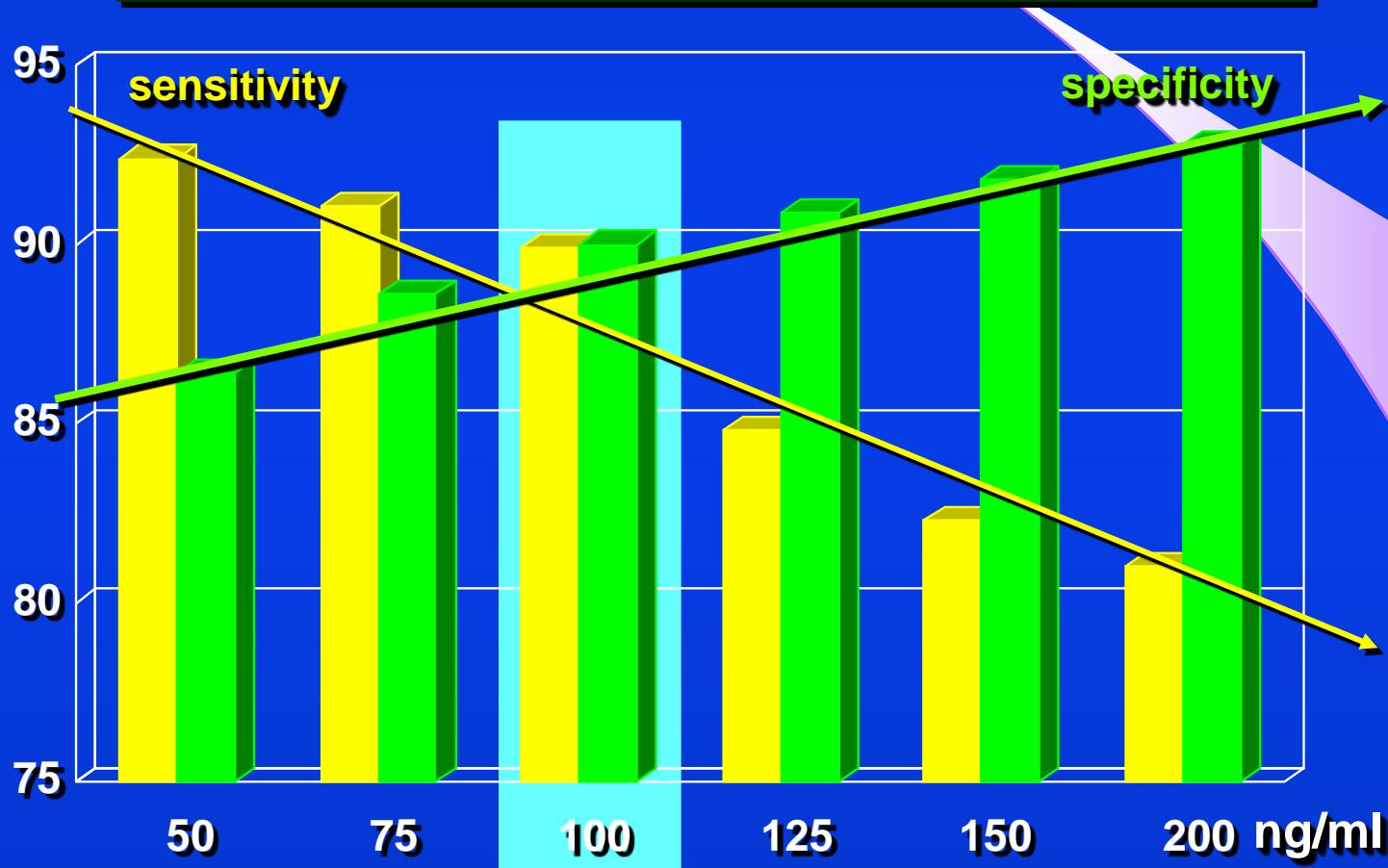
Terhaar sive Droste JS, Oort FA, van der Hulst RW. et al.

Cancer Epidemiol Biomarkers Prev; 20(2) February 2011

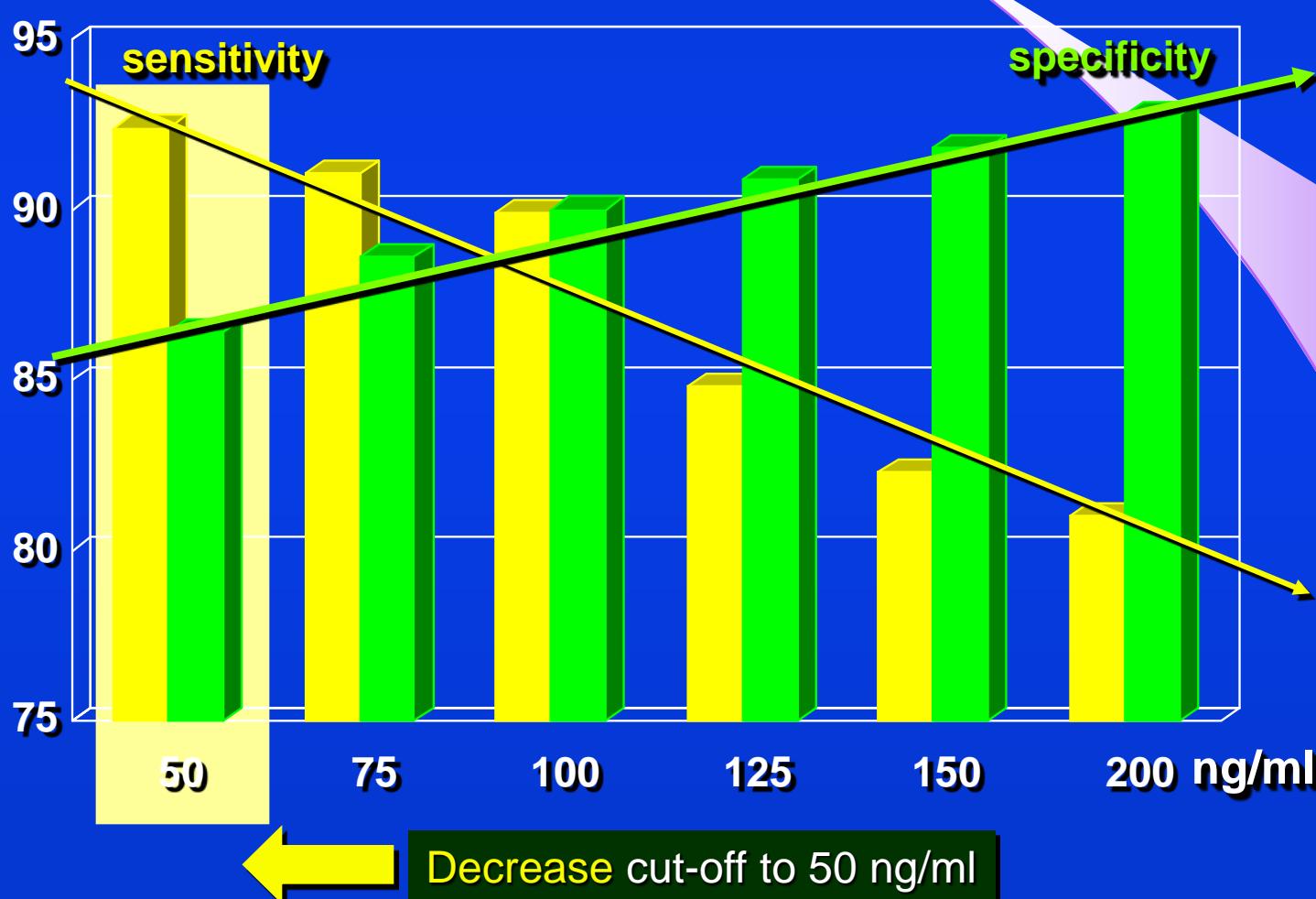
Higher fecal immunochemical test cutoff levels: lower positivity rates  
but still acceptable detection rates for early-stage colorectal cancers.



OC-Sensor Eiken recommended cut-off value **100 ng/ml**  
with similar sensitivity & specificity approximately **90 %**

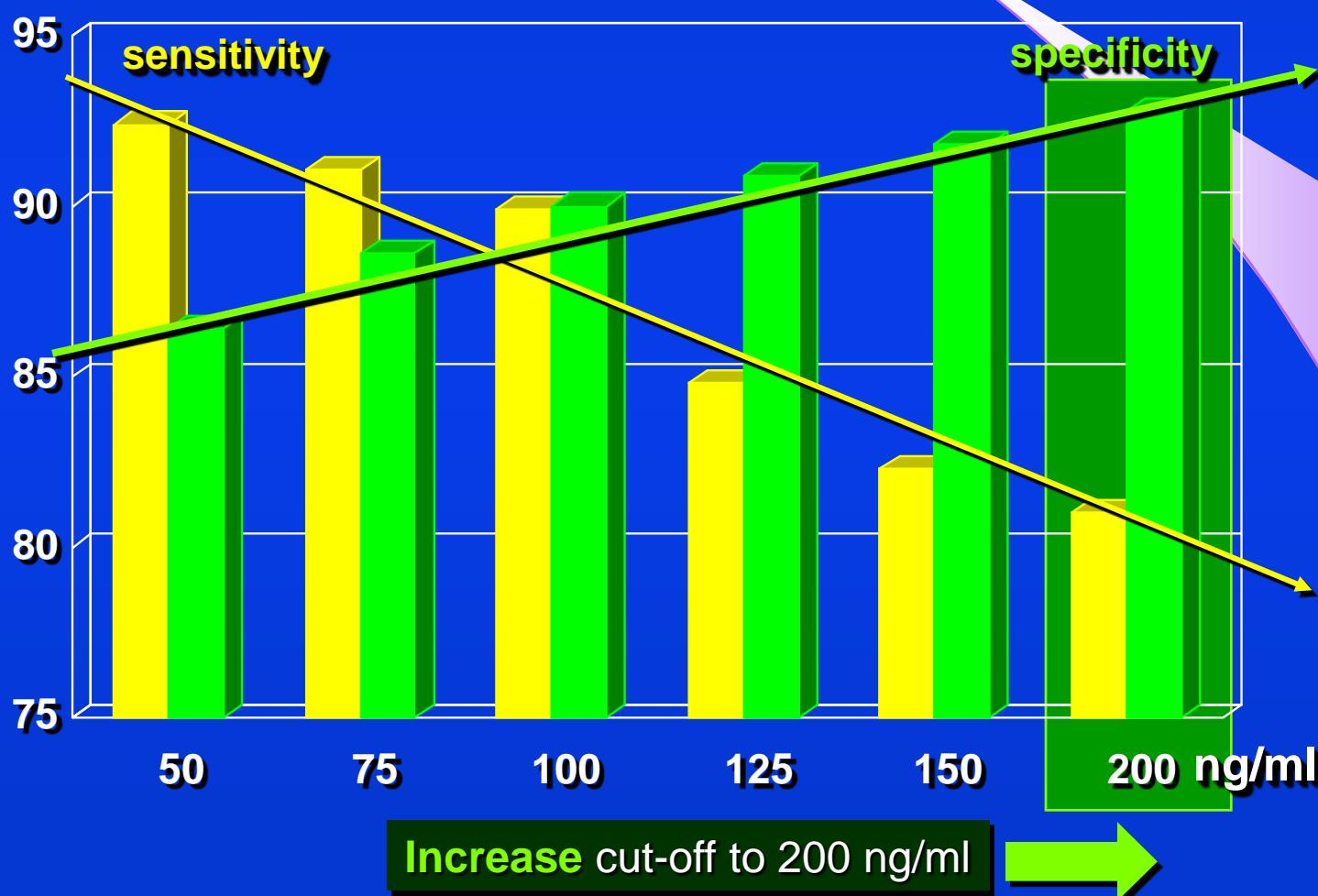


Optimizing cut-off for qFOBT and indications for colonoscopy:  
Indicate for colonoscopy, if possible, **all pathology**,  
**including 15% of healthy people?** The **sensitivity could be 93%**.





Optimizing cut-off for qFOBT and indications for colonoscopy:  
Do **not indicate** for colonoscopy **any healthy person**,  
increase **specificity** to **93%** but **reduce the sensitivity by 15%**?





## FOBT - THE FUTURE

PREMISE - VISIONS - SIX MAIN TASKS

ANALYSE THE EUROPEAN EXPERIENCES  
HIGHLIGHT QUANTITATIVE FIT  
CLEARLY DEFINE CUT-OFF POSITIVITY

### 4. TASK

CHANGE THE Hb CONCENTRATION UNIT

## UNITS &amp; CUT-OFF VALUE (ng Hb/ml / mg Hb/g stool)

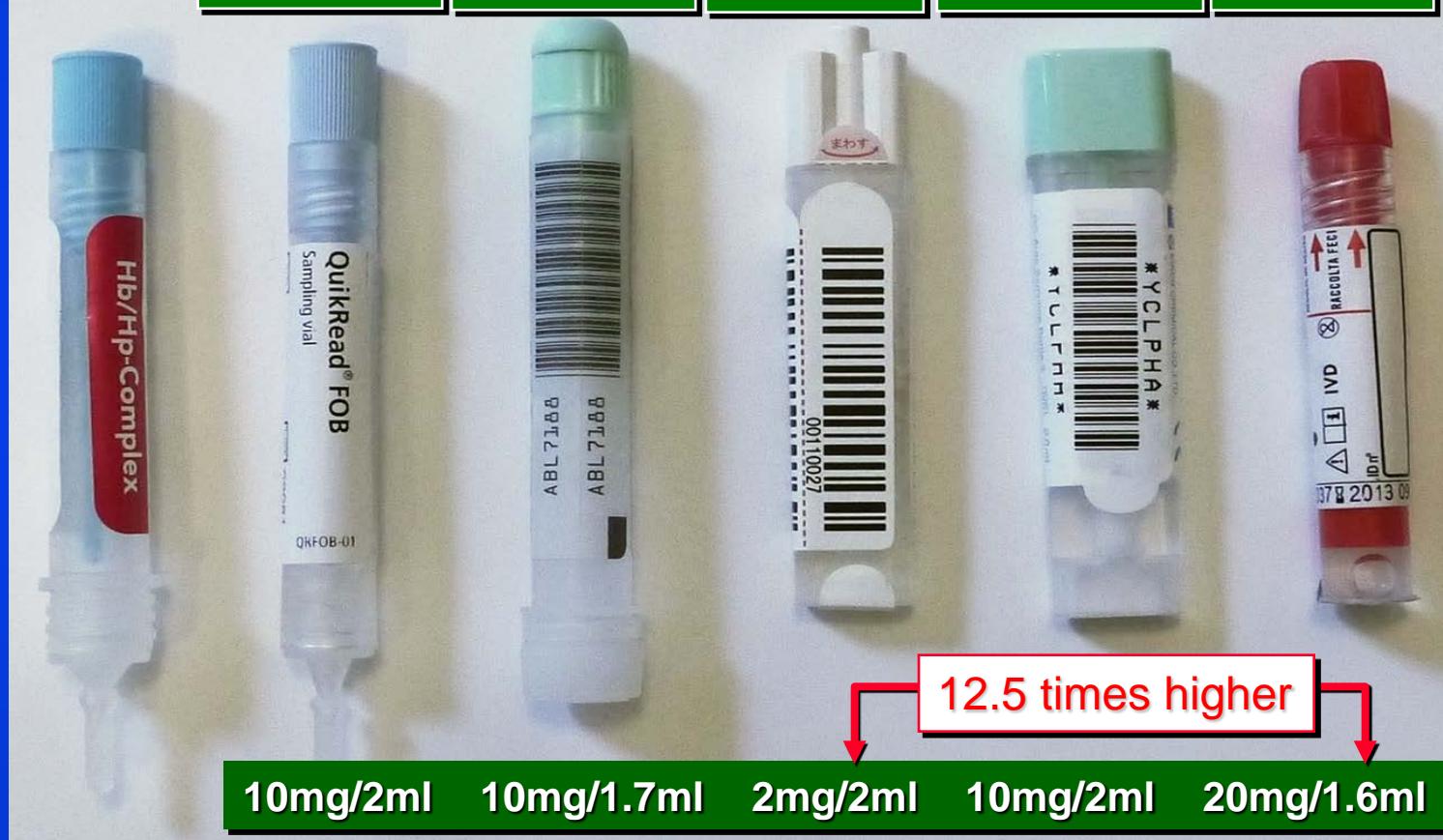
QuikRead

FOB Gold

HM Jack

OC Sensor

iT Linear

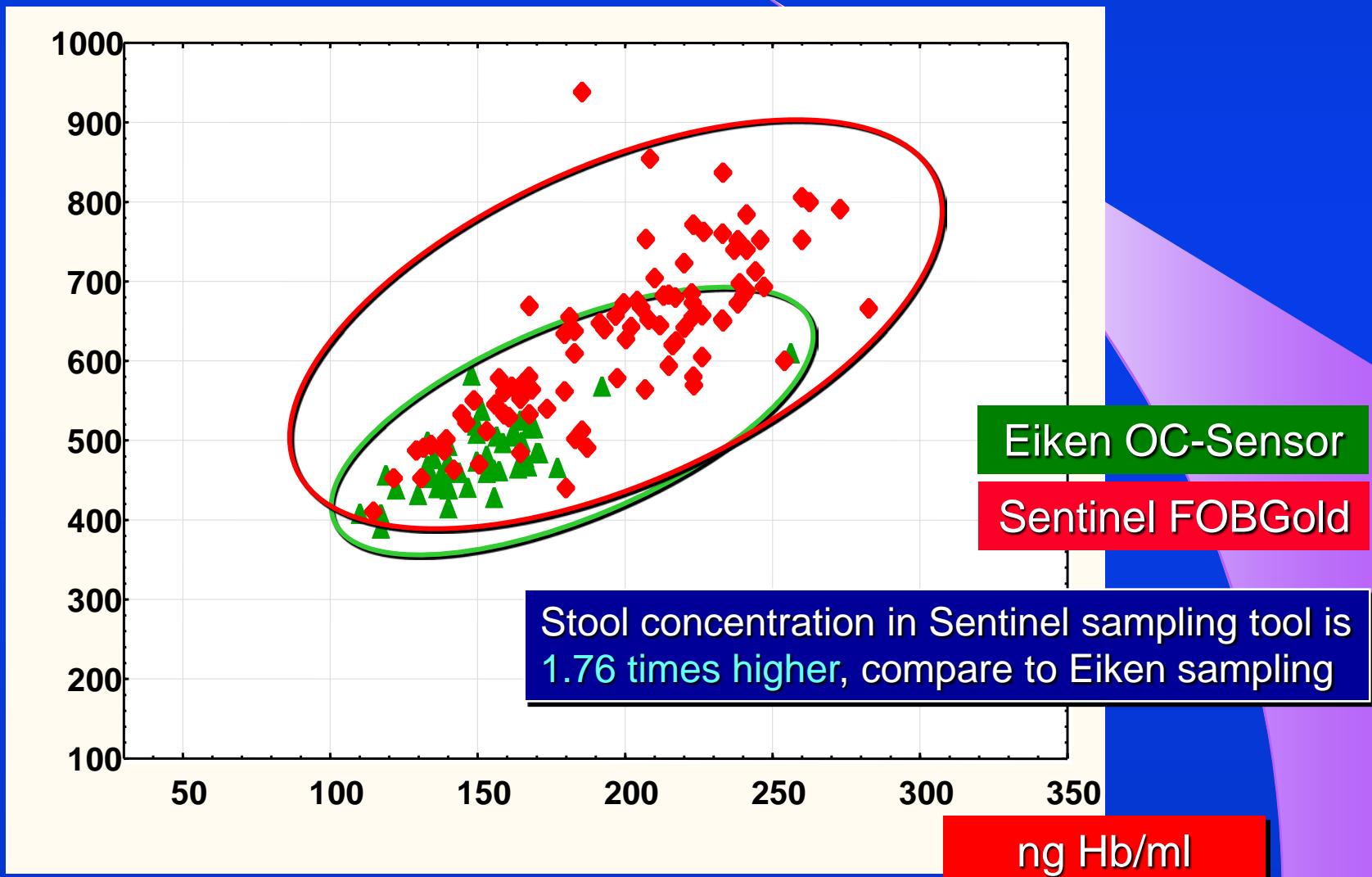


10mg/2ml    10mg/1.7ml    2mg/2ml    10mg/2ml    20mg/1.6ml

VARIABLE SAMPLING DEVICES FOR FIT, WITH DIFFERENT CONCENTRATION OF STOOL IN THE SAMPLING SOLUTION

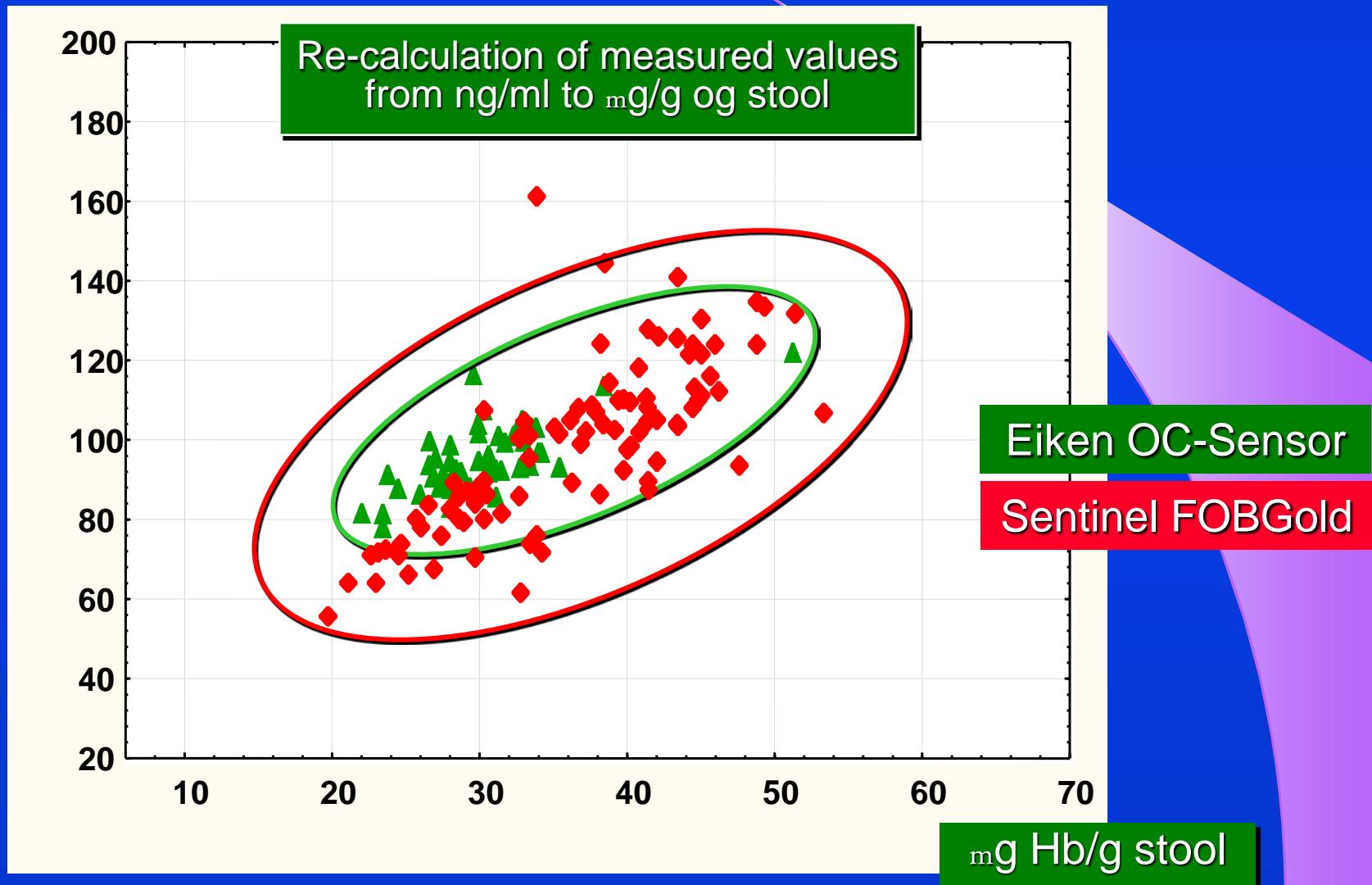


## UNITS & CUT-OFF VALUE (ng Hb/ml / mg Hb/g stool)





## UNITS & CUT-OFF VALUE (ng Hb/ml / $\text{mg Hb/g}$ stool)





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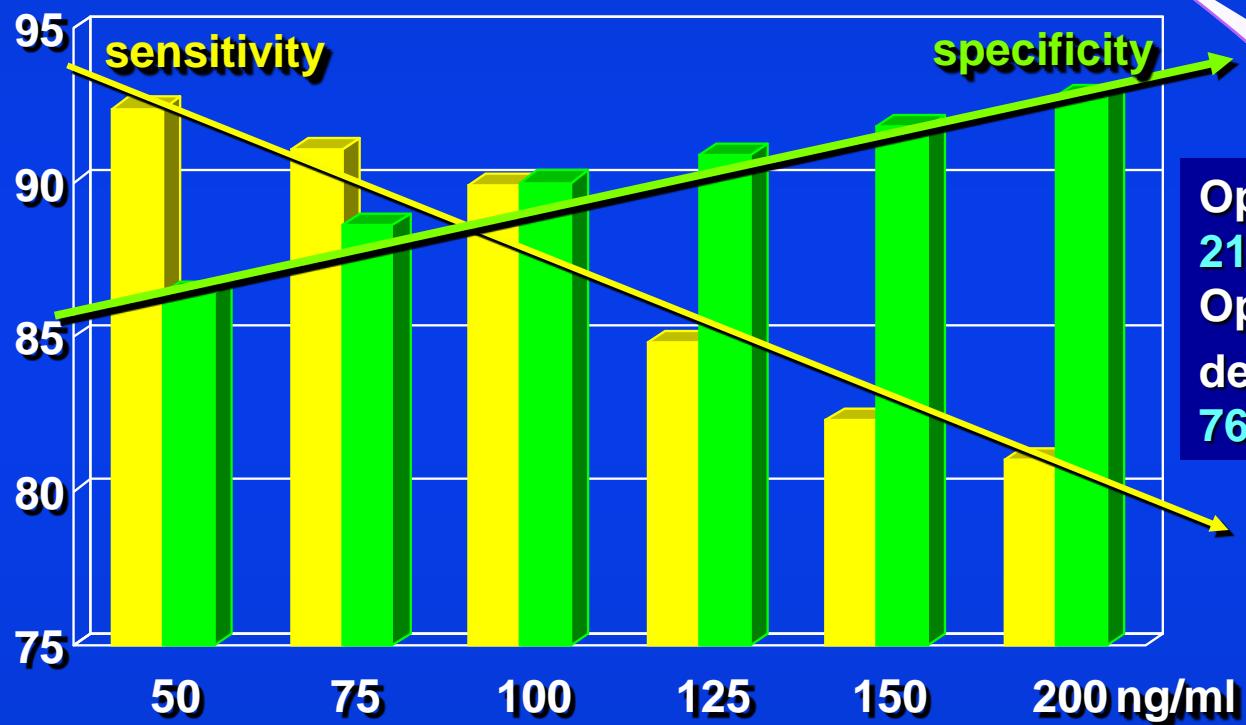
PREMISE - VISIONS - SIX MAIN TASKS

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HIGHLIGHT QUANTITATIVE FIT  
CLEARLY DEFINE CUT-OFF POSITIVITY  
CHANGE THE Hb CONCENTRATION UNIT

### 5. TASK

MODIFY THE SCREENING RULES

## Cancer Epidemiol Biomarkers Prev - 2011



**Optimization FIT cut-off**  
**2145 persons > 40 years**  
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**define the minimum age**  
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Higher fecal immunochemical test cutoff levels: lower positivity rates  
but still acceptable detection rates for early-stage colorectal cancers.



## Clinical Gastroenterol Hepatol. - 06/2012



Local studies with 9,800 inhabitants, 3,145 aged 50-74 years  
FIT test OC-Sensor, 100 ng/ml, performed 2001-2003-2006-2008  
Participation in four cycles from 56% to 63%, 48.1% of all 4 cycles

Cycle	2001	2003	2006	2008
Invited	2959	2566	2056	1862
Participated	2161	1520	971	713
FIT positivity	92 (4,3%)	62 (4,1%)	33 (3,4%)	36 (5,1%)
CRC+AA detected	35	18	10	12

Local studies with 4 cycles lasting 8.5 year with the participation  
of 48% of the population in all cycles  
Screening - quantitative FIT with cut-off of 100 ng/ml

Crotta S, Segnan N, Paganin S, et al. Clin Gastro.Hepato. 2012;10(6):633-638  
High rate of advanced adenoma detection in 4 rounds of colorectal cancer  
screening with the fecal immunochemical test.



## DETECTED COLORECTAL CANCERS

AGE 50 – 90 YEAR ( n = 4145 )

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Patients specialized hospital clinics outpatient and inpatients

Detected CRC – 53/64

Kocna P., Májek O., Blaha M., Zima T., Dušek L.: Characteristics of colorectal cancer detected by quantitative faecal haemoglobin test in hospital opportunistic screening.  
WorldLab 2014, June, Istanbul



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PREMISE - VISIONS - SIX MAIN TASKS

ANALYSE THE EUROPEAN EXPERIENCES  
HIGHLIGHT QUANTITATIVE FIT  
CLEARLY DEFINE CUT-OFF POSITIVITY  
CHANGE THE Hb CONCENTRATION UNIT

### 5. TASK

MODIFY THE SCREENING RULES

- could we change screening age limits **since 40 year** ?
- could we include **annually FIT test** even after colonoscopy ?
- could we increase number of FIT tested subjects including **indications from specialized hospital clinics - diabetology, cardiology etc** ?



## FOBT - THE FUTURE PREMISE - VISIONS - SIX MAIN TASKS

ANALYSE THE EUROPEAN EXPERIENCES  
HIGHLIGHT QUANTITATIVE FIT  
CLEARLY DEFINE CUT-OFF POSITIVITY  
CHANGE THE Hb CONCENTRATION UNIT  
MODIFY THE SCREENING RULES

### 6. TASK

INCREASE EDUCATION UNIVERSALLY



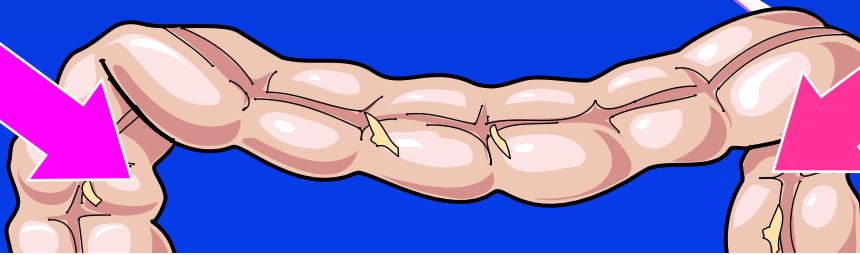
## EDUCATION ON IMPORTANCE OF FIT VALUES

1/11

9.1%

1/  
8

12.5%



False negativity - is 15.62 %

(cut-off value 75 ng/ml recommended by the CRC Commission)

The sensitivity for CRC - is 84.38 %

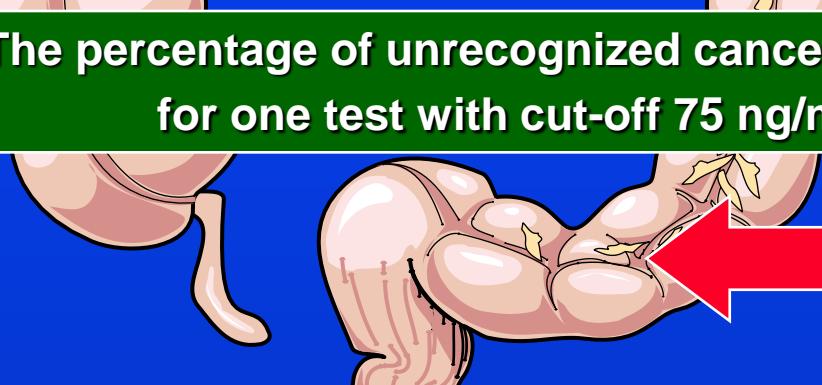
3/16

18.7%

5/29

17.2%

The percentage of unrecognized cancers - 17.6%  
for one test with cut-off 75 ng/ml



Kelley L, Swan N, Hughes DJ. - Colorectal Dis. 2013 Sep; 15(9): e512-21  
An analysis of the duplicate testing strategy of an Irish immunochemical FOBT colorectal cancer screening programme



## EDUCATION ON IMPORTANCE OF FIT VALUES

**Man 66 year (born 1946)**

**29.4.2009 - FIT: 0 ng/ml**

**8.8.2011 - FIT: 1355 ng/ml**

**NO reaction**

**11.7.2012 - FIT: 1854ng/ml**

14.8.2012 - colonoscopy, sigmoid CRC

6.9.2012 - tumour resection, stage 3

FIT - surgery time: **12.96 months**

Two cases with  
FIT value 0 ng/ml and CRC

**Man 72 year (born 1941)**

**13.5.2010 - FIT: 0 ng/ml**

**14.11.2012 - FIT: 741 ng/ml**

**NO reaction**

**5.3.2013 - FIT: 1637 ng/ml**

10.4.2013 - colonoscopy, sigmoid CRC

13.5.2013 - tumour resection, stage 3

FIT - surgery time: **5.92 months**

**Kocna P., Májek O., Blaha M.: Clinical and epidemiological importance  
of analyzing laboratory data with the data source I-COP.  
Sborník Medsoft 2014 - March 25; 110-122  
on-line: <http://creativeconnections.cz/medsoft/2014.html>**



## EDUCATION ON IMPORTANCE OF FIT VALUES

- ✓ FIT value 0 ng/ml does not mean, that there is no cancer
- ✓ Quantitative FIT with sensitivity 85% does not recognize 15% of CRC
- ✓ Repeated FIT screening, annually, are very important
- ✓ FIT value more than 1000 ng/ml being almost reliably indicates cancer and colonoscopy should be performed as soon as possible



## FOBT - THE FUTURE

### PREMISE - VISIONS - SIX MAIN TASKS

- ✓ ANALYSE THE EUROPEAN EXPERIENCES
- ✓ HIGHLIGHT QUANTITATIVE FIT
- ✓ CLEARLY DEFINE CUT-OFF POSITIVITY
- ✓ CHANGE THE Hb CONCENTRATION UNIT
- ✓ MODIFY THE SCREENING RULES
- ✓ INCREASE EDUCATION UNIVERSALLY



**THANK YOU FOR YOUR ATTENTION**