

**False negatives**  
**In FIT screening due to**  
**delayed return of faecal samples**

Int J Cancer. 2009 Apr 2. [Epub ahead of print]

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**Background** 

IMMUNOCHEMICAL FAECAL OCCULT BLOOD TESTS (FIT)

- promising in screening
- High detection rates (*relatively*)
- High participation rates

*by direct mailing and testing at home*

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**Background** 

- Quantitative ('wet') FITs:
  - *Advantage:* cut-off value can be changed
  - *Disadvantage:* 'wet' and therefore *less stable*
- Wet is stable at refrigerator temperatures or lower
- Less at room temperature or higher
- Implications for implementation uncertain (*especially in designs with direct mailing and at home testing*)

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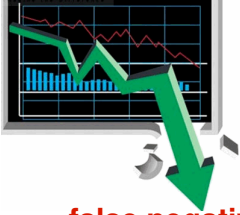
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**Aim of the study** UMC St Radboud

haemoglobin degradation  
FIT faecal sample



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**Study: 2 parts** UMC St Radboud

Part 1: "in the field"

- *self-reported* sampling date
- delivery date - sampling date = delay
- delay ↑ = % true positives ↓?

*Limited number late responders*

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**Study: 2 parts** UMC St Radboud

Part 1: "in the field"

- *self-reported* sampling date
- delivery date - sampling date = delay
- delay ↑ = % true positives ↓?

*Limited number late responders*

Part 2: laboratory confirmation

- retest positives

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# OMED COLORECTAL CANCER SCREENING COMMITTEE MEETING

Saturday, May 30, DDW Chicago, 2009

Presenter: L. van Rossum

**Part 1: design** UMC St Radboud

**“in the field”**

self-reported sampling date

Days delay	1-4	≥5	≥7
Positives	%	%	%
True positives	%	%	%

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**Part 1: data delayed tests** UMC St Radboud

sample date reported

Delay days*	1-4	≥5	≥7
Number	3062	705	195
<b>Positive</b>	<b>8.7%</b>	<b>6.0%</b>	<b>4.1%</b>
Colonoscopy	85%	81%	67%
<b>Detection Rates</b>			
Adenomas	<b>4.7%</b>	<b>2.8%</b>	2.1%
Advanced Adenomas	2.7%	1.7%	1.0%
Colorectal Cancer	0.3%	0.9%	0.5%

8 =statistically significant

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**Part 2: population** UMC St Radboud

**laboratory confirmation**

Positives (≥50ng/ml): 170

Colonoscopy: 139 (82%)

- Adenoma: 79 (57%)
- Advanced: 45 (32%)
- Carcinoma: 8 (6%)

9 equal percentages in the overall study

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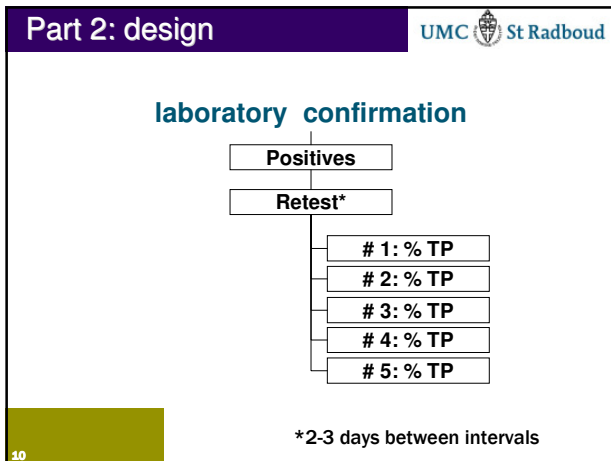
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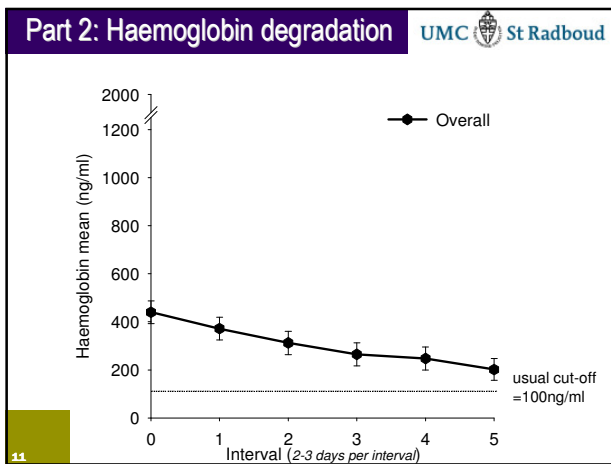
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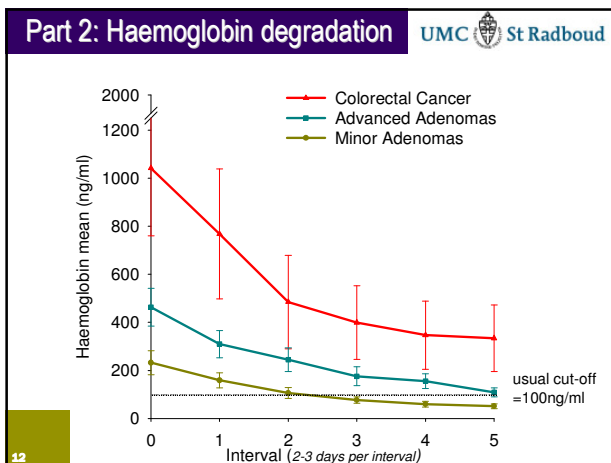
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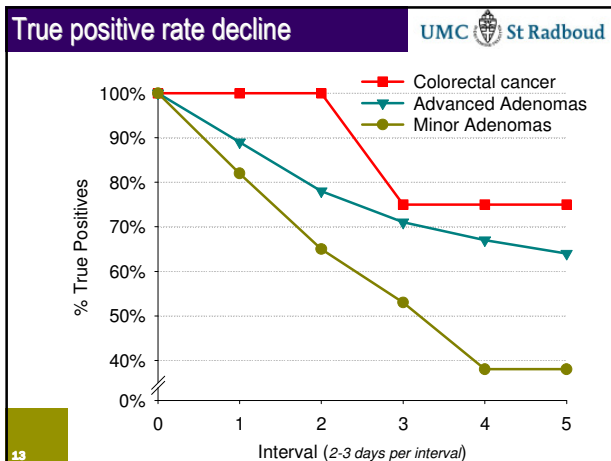
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### Conclusion

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- performance decreased with limited delay
- minor adenomas missed early
- advanced adenomas fairly early
- stage I cancer eventually
- later stages not or late

Screening Advantageous

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### All quantitative 'wet' FITs !

UMC St Radboud

THE HON NICOLA ROXON MP  
Australian Minister for Health and Ageing

MEDIA RELEASE

SELF-TEST BOWEL CANCER KITS

I am very concerned that the results provided to some participants in the National Bowel Cancer Screening Program may not be accurate. I am advised that these

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# OMED COLORECTAL CANCER SCREENING COMMITTEE MEETING

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**Implications and solutions** UMC St Radboud

- Postal services  climate 
- Solutions *can be combined*:
  - different cut-off values? *NOT Possible*
  - do not invite in 'hot' seasons
  - monitor delay
  - repeat test after delay?  
*if not positive or not absolutely negative*
- MORE STABLE SOLUTION!**

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