

"Life sciences for health and innovation"

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Photo: Jarle Bruun

# Biomarkers for non-invasive testing for colorectal cancer

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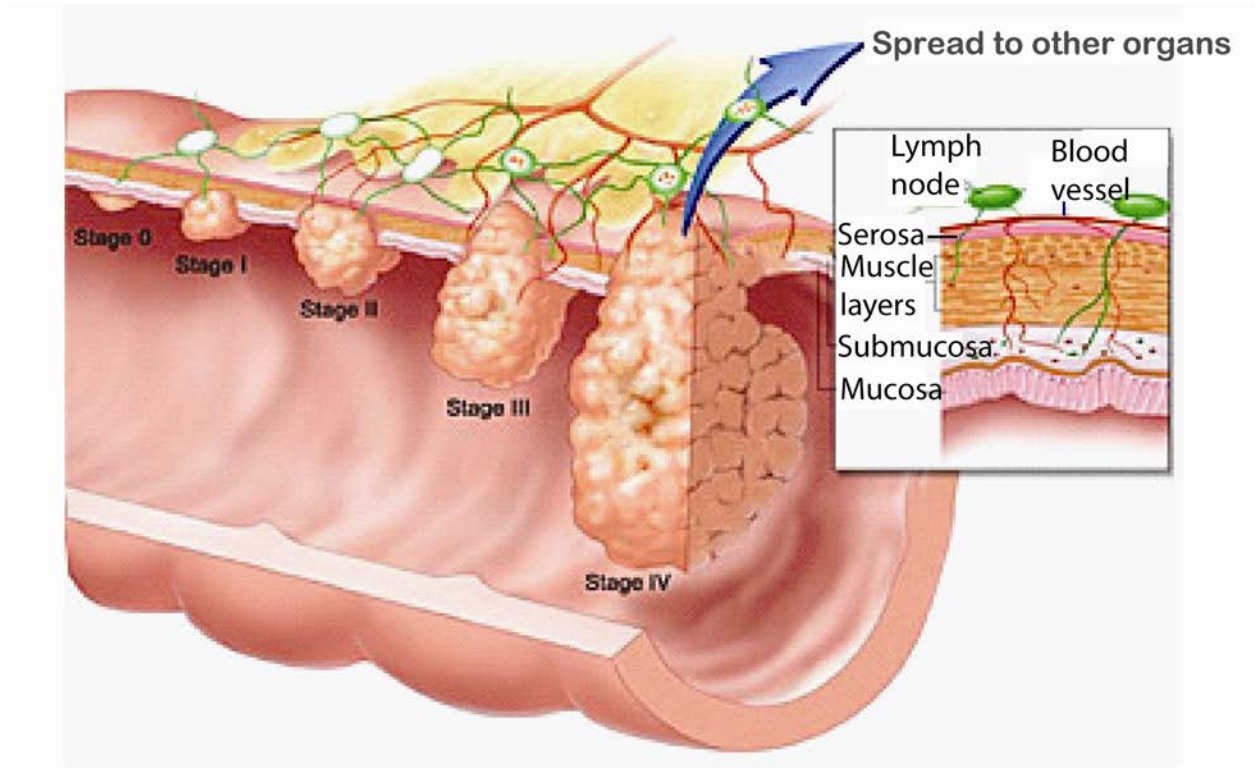


Illustration is modified from National Cancer Institute

# Early diagnosis will improve patient survival

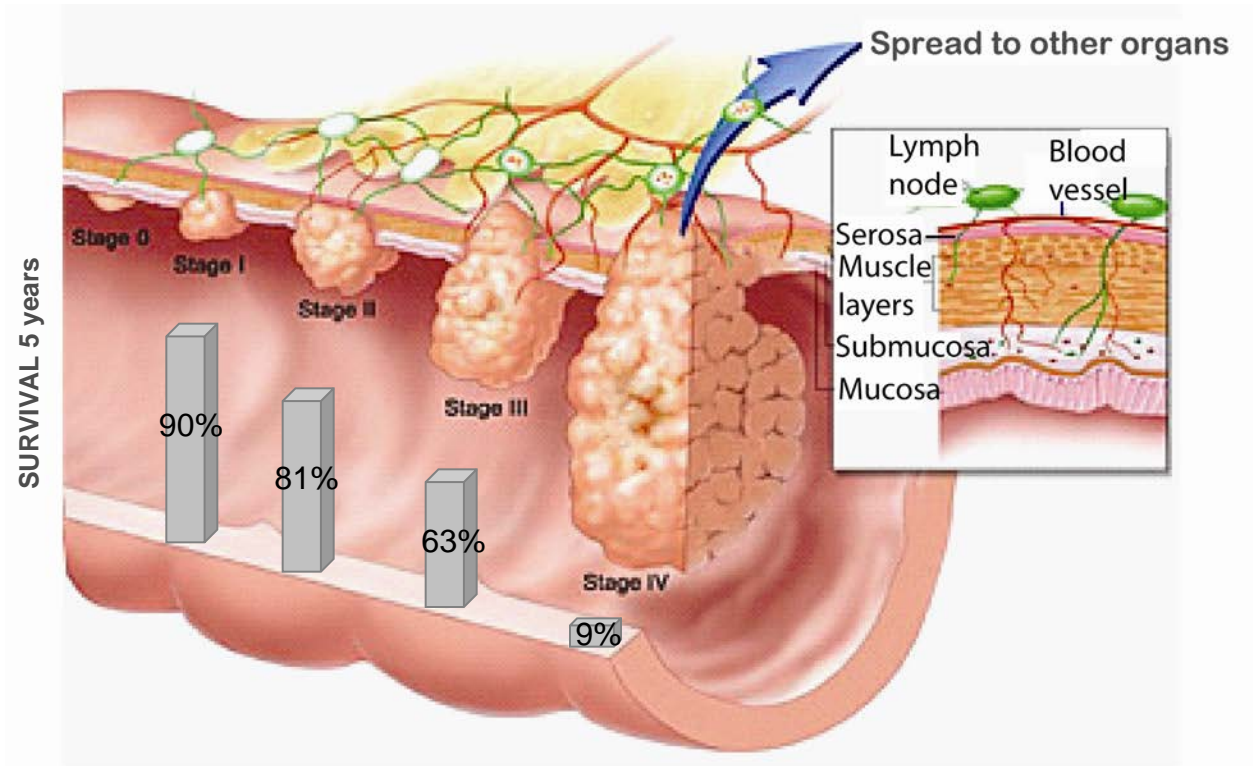
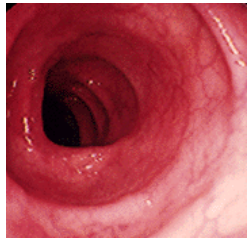


Illustration is modified from National Cancer Institute

Survival: data from the Norwegian Cancer Registry, 2009

# "Window of opportunity" for diagnostics



Normal  
mucosa



Small  
adenoma



Intermed.  
adenoma



Large  
adenoma



Carcinoma →

Diagnostics

5-35 years →

## FOBT = fecal occult blood test

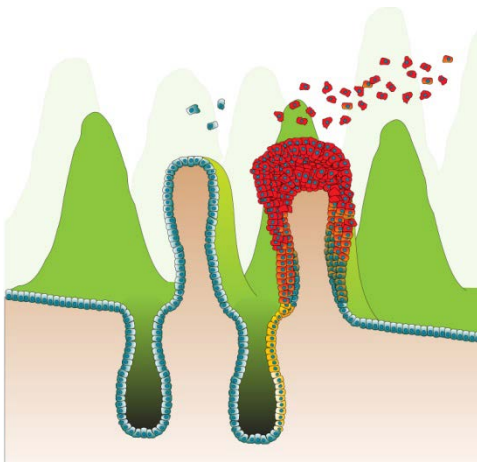
Well established, simple, reduce mortality of CRC  
Unspecific, limited sensitivity, and limited detection of precursors (adenomas)

## Fecal DNA test

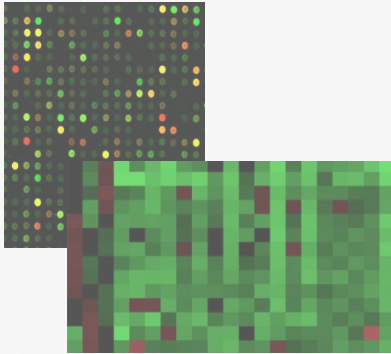
Limited sensitivity and specificity  
-The ColoSure test. Methylation marker, VIM

## Blood/plasma/serum test

-Epi ProColon test. Methylation marker, SEPT9.



## Experimental pipeline



## Six biomarkers identified



## Results

- New strategy for identification of methylated candidates  
*Lind et al Cell. Oncol. 2006*
- Proof-of-principle  
*Lind et al Gastroenterology 2007*
- Clinical validation of first biomarker  
*Lind et al J Transl Med. 2008*
- Methylation in precursor lesions  
*Ahlquist et al Mol Cancer. 2008*
- Panel of biomarkers published  
*Lind et al Mol Cancer. 2011*
- Analysis of biological function  
*Lind et al Oncogene. 2011*

## Innovation/development

- DOFI signed, patent application 2007
- PCT/EP2008  
PA published, WO 2008/102002 2008
- R&D, TTO  
Biotech conferences 2009
- MTA phase I-II signed  
Eur Biotech comp 2010
- License agreement? 2011

# Clinical test and validation series



Normal mucosa → Small adenoma → Intermed. adenoma → Large adenoma → Carcinoma →

Normal

Benign

Malignant

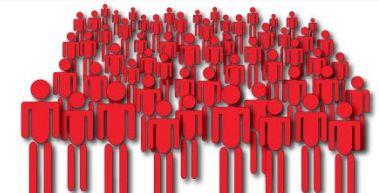
Test



N = 51



N = 61



N = 80

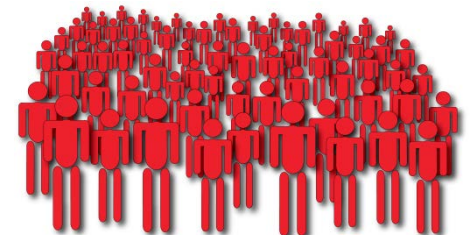
Validation



N = 59



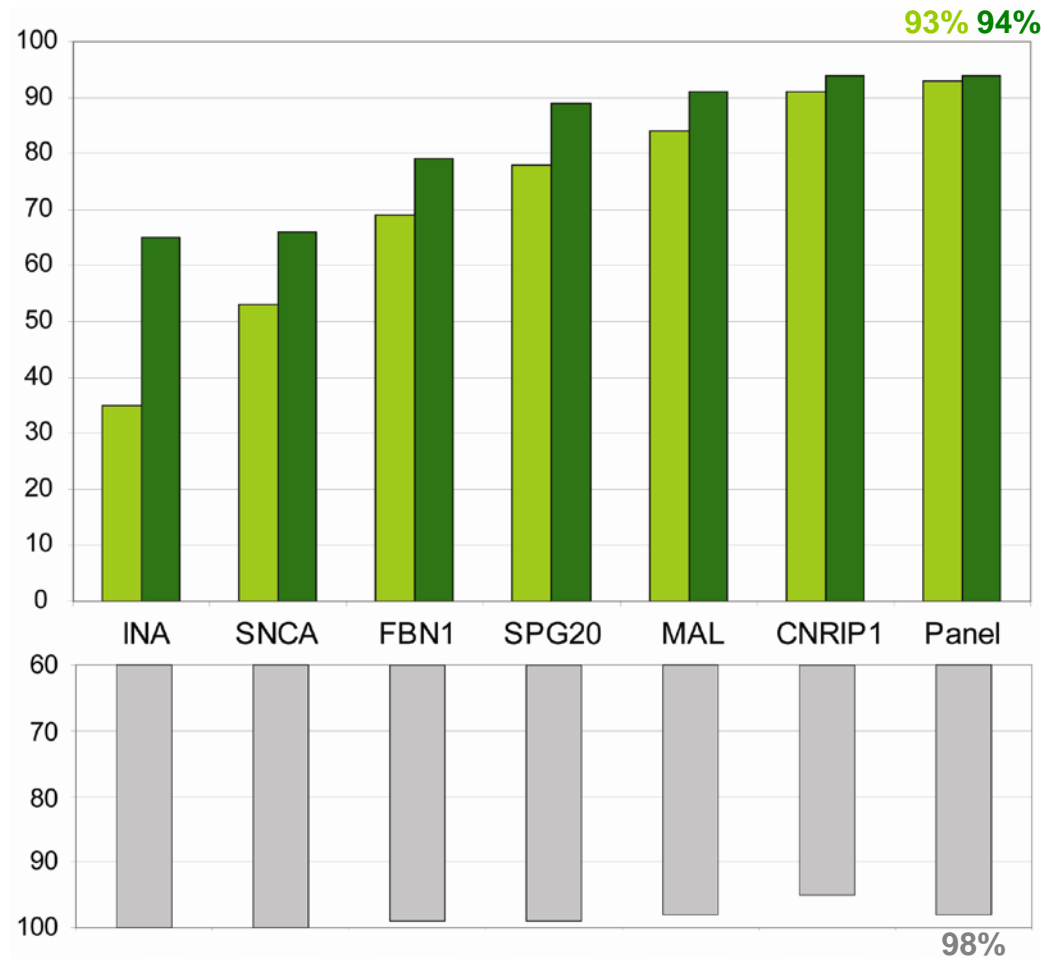
N = 52



N = 105

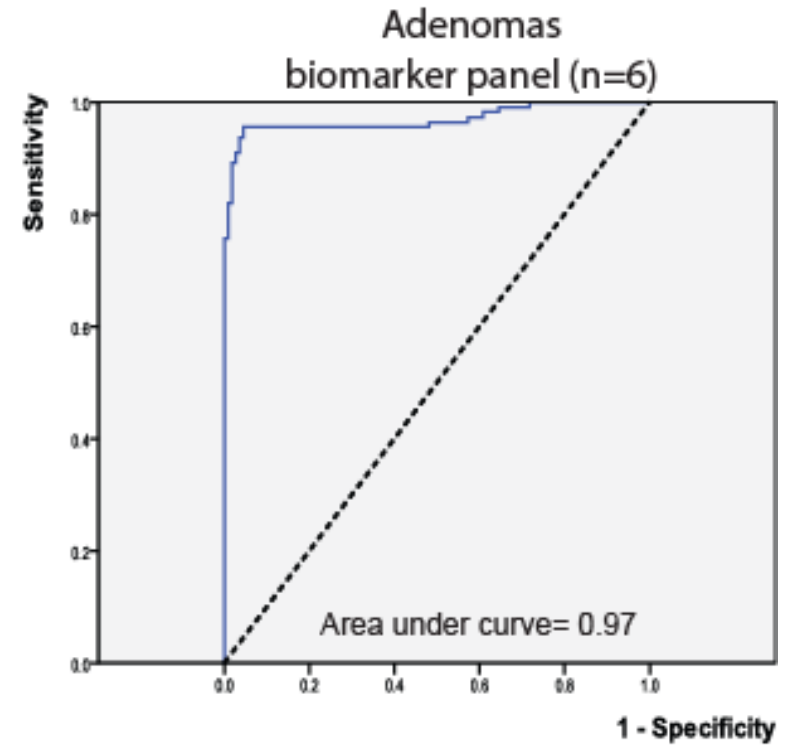
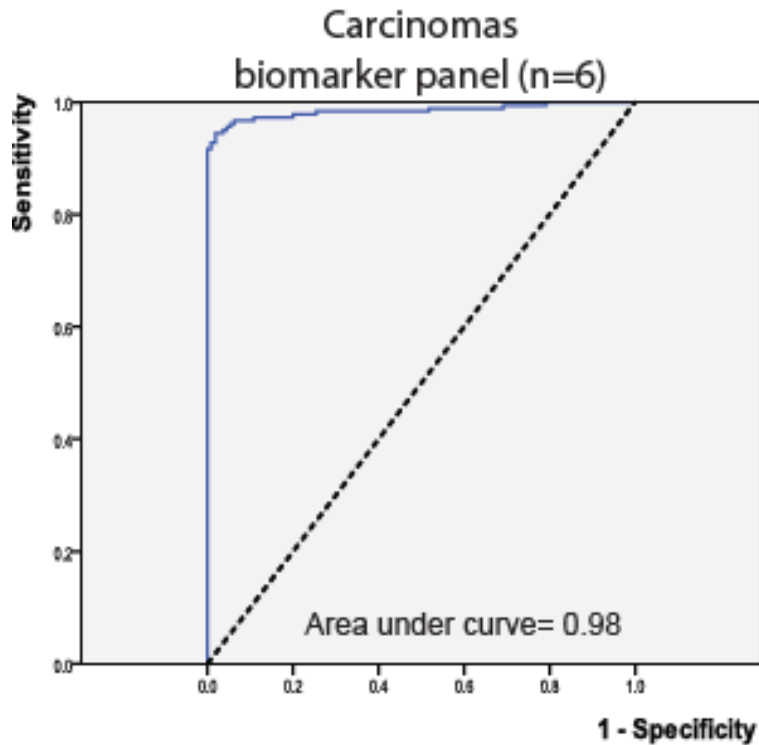
Sensitivity  
Adenoma (n=111)  
Carcinoma (n=179)

Spesificity  
Normal mucosa  
n=110





# ROC confirms high sensitivity and specificity



# "Clinical proof of concept": Non-invasive testing using fecal samples

Normal



N = 30



Normal mucosa  
Fecal samples  
Blood samples

Benign

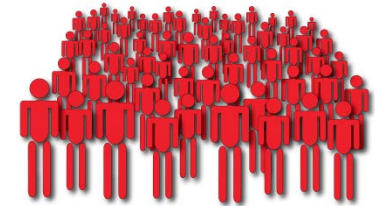


N = 30



Adenomas  
Fecal samples  
Blood samples

Malignant



N = 72



Carcinomas  
Fecal samples  
Blood samples

NordICC screening



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- Prof. Geir Hoff



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Group leader and head of Department

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