

Is Cologuard the new high bar for non-invasive CRC screening

"No"

Douglas J. Robertson, MD MPH
Geisel School of Medicine at Dartmouth
Hanover, NH
VA Medical Center
White River Junction, VT

Multitarget Stool DNA Testing for Colorectal-Cancer Screening

Thomas F. Imperiale, M.D., David F. Ransohoff, M.D., Steven H. Itzkowitz, M.D.,

Test	Sensitivity	
	Cancer (n=65)	Advanced Neoplasia (n=757)
sDNA	92.3%	42.4%
FIT	73.8%	23.8%

N=9989

N Engl J Med. 2014 Apr 3;370(14):1287-97

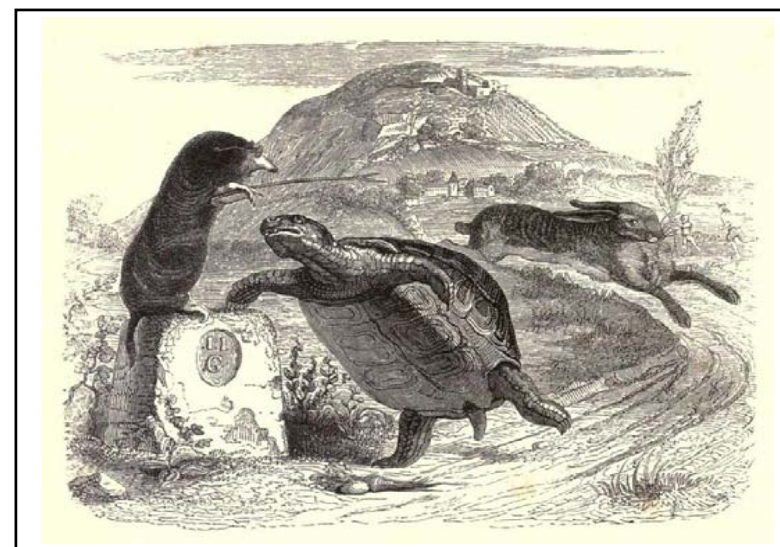
Multitarget Stool DNA Testing for Colorectal-Cancer Screening

Thomas F. Imperiale, M.D., David F. Ransohoff, M.D., Steven H. Itzkowitz, M.D.,

Test	Detection	
	Cancer (n=65)	Advanced Neoplasia (n=757)
sDNA	60	321
FIT	48	180
Colonoscopy	65	757

N=9989

N Engl J Med. 2014 Apr 3;370(14):1287-97



Multitarget Stool DNA Testing
for Colorectal-Cancer Screening

Thomas F. Imperiale, M.D., David F. Ransohoff, M.D., Steven H. Itzkowitz, M.D.,

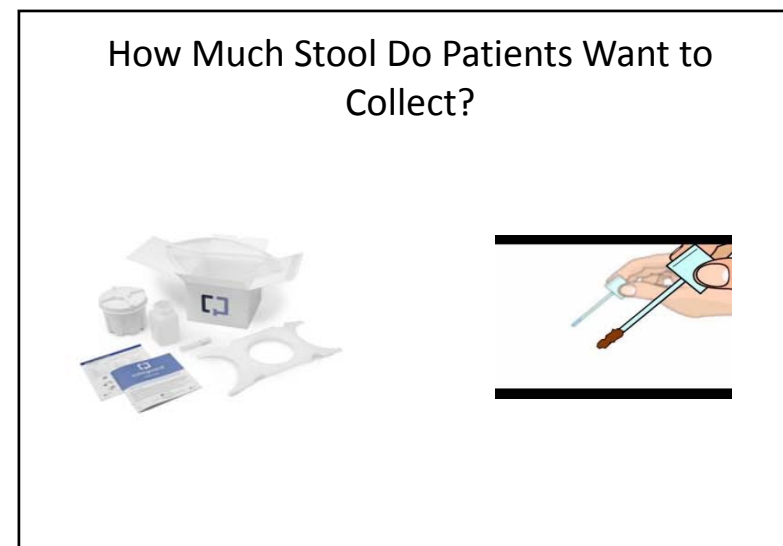
Test	Specificity= Entirely Negative Colonoscopy	Specificity= Entirely Negative Colonoscopy & Non advanced lesions
Stool DNA	89.8%	86.6%
FIT	96.4%	94.9%

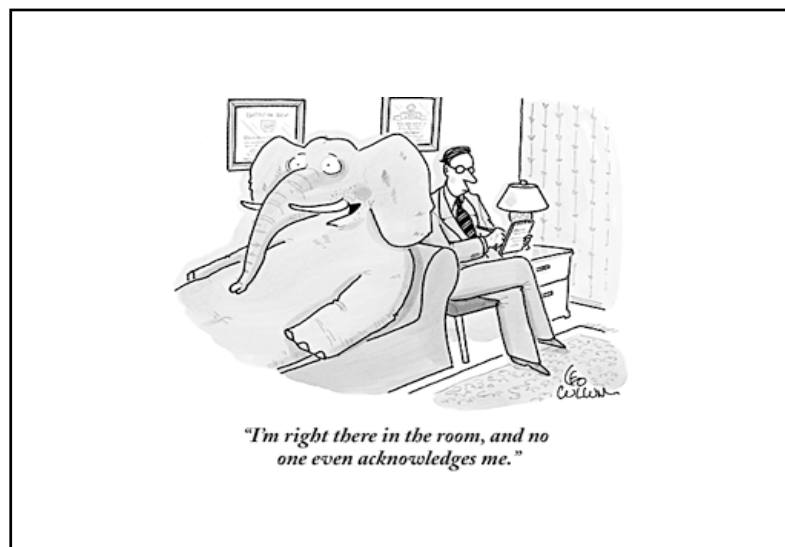
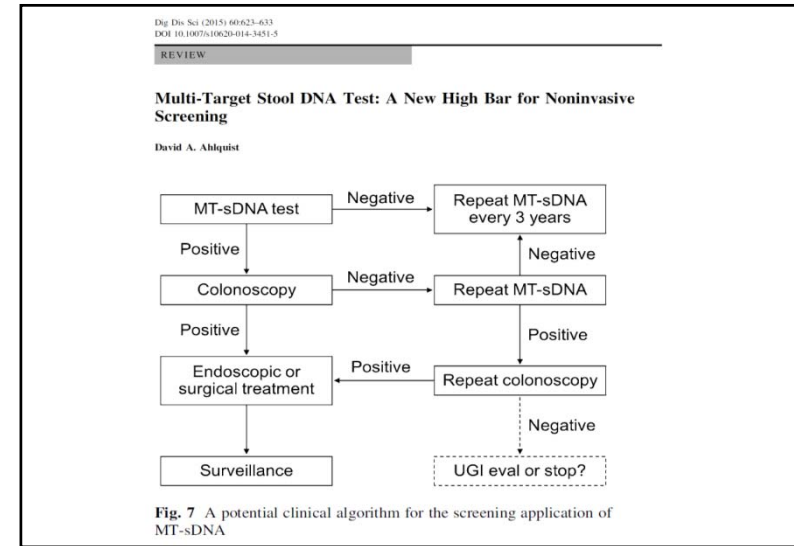
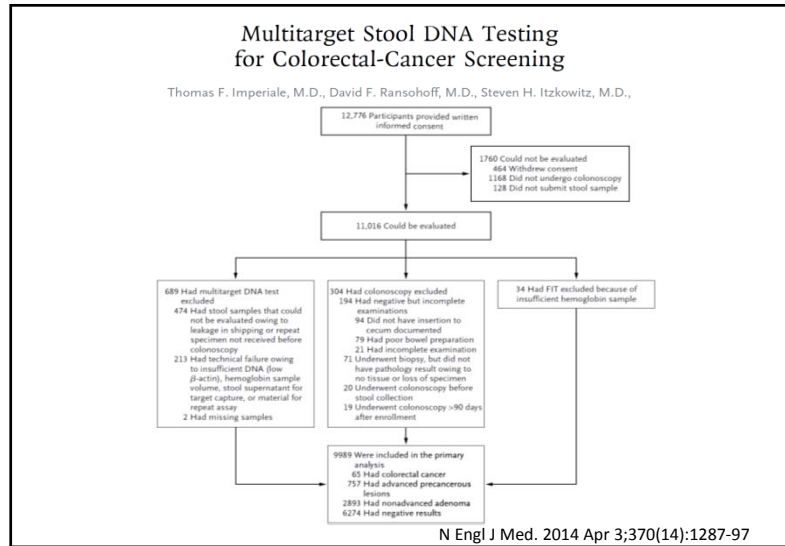
N=9989

N Engl J Med. 2014 Apr 3;370(14):1287-97

- ## Practical Considerations
- Compliance
 - Follow up
 - Cost

- ## Colonoscopy versus Fecal Immunochemical Testing in Colorectal-Cancer Screening
- ▶ RCT of invitation to either colonoscopy or FIT (n=53,302)
 - ▶ Interim results after one round of screening
 - ▶ Low participation in both FIT (34.2%) and colonoscopy (24.6%) groups
- Findings
- ▶ Cancer
 - ▶ Colonoscopy Arm = 30 (4 found by cross-over to FIT)
 - ▶ FIT Arm = 33 (1 found by cross-over to colonoscopy)
 - ▶ Advanced neoplasia
 - ▶ Colonoscopy Arm =514
 - ▶ FIT Arm = 231
- Quintero and Castells N Engl J Med 2012;366:697-706

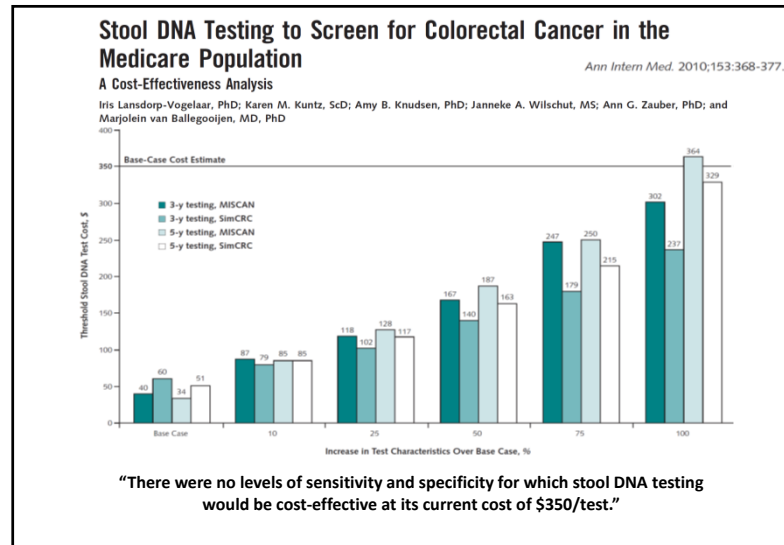




	One time cost	Cycles/10 yrs	Total
FIT	~\$20	10	\$200
sDNA	~\$500	3	\$1500

- More False Positives → extra colonoscopy
- More work up when test is positive & colo negative

Test	Cancer Detection	Recommended Interval if negative
Stool DNA	60	q 3(??)
FIT	48	q 1-2



- ### A New High Bar? “No”
- A more difficult test to complete successfully
 - Will impact compliance
 - Too many false positives
 - detecting non advanced adenomas is a disadvantage
 - Uncertainties about the follow up when the test is positive
 - Are we even sure about q 3 when negative?
 - Cost
 - Upfront & downstream related to work up

CLINICAL GASTROENTEROLOGY AND HEPATOLOGY 2012;10:633-638

High Rate of Advanced Adenoma Detection in 4 Rounds of Colorectal Cancer Screening With the Fecal Immunochemical Test

SERGIO CROTTA,¹ NEREO SEGNAN,¹ SIMONA PAGANIN,¹ BRUNA DAGNES,² ROBERTO ROSSET,³ and CARLO SENORE¹

	1	2	3	4
N examined	2161	1520	971	713
% positive	4.3%	4.1%	3.4%	5.4%
Advanced Adenoma PPV%	34.5%	31.5%	27.6%	33.3%
Cancer PPV %	5.8%	1.9%	6.9%	0