

# Test Characteristics of a One-time, Single-sample Fecal Immunochemical Test for Persons at Average Risk for Colon Cancer

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## Background

Among individuals 50 years and older, colon cancer is the third leading cause of cancer death. This form of cancer can often be cured if caught early. Colonoscopy is the standard for colon cancer detection and is recommended every ten years, however annual fecal immunochemical testing (FIT) may result in similar life-years gained compared to decennial colonoscopy. **The purpose of this study was to determine the test characteristics of a one-time, single-sample FIT vs. colonoscopy for detecting ? in individuals at average risk for colon cancer.**

## Design

**Prospective screening study.** Individuals scheduled for screening or surveillance colonoscopy at UIOWA Hospital & Clinics were invited to participate in this study. Subjects invited were 40 -75 years old, did not have a history of familial polyposis syndromes, ulcerative colitis, Crohn's disease, or colon cancer, along with no active rectal bleeding, recent changes in bowel habits, or pencil-like stools. Subjects received a recruitment package with a FIT kit and were instructed to use it shortly before beginning colonoscopy prep. Recruitment packages were mailed from January 22, 2010 to November 22, 2011. Due to unforeseen events, four different FIT manufacturers were used throughout the study. Test characteristics (sensitivity, specificity, PPV, NPV, LR+, and LR-) for the FITs were calculated by using the subjects' respective colonoscopies as the gold standard. A positive colonoscopy was defined as: an adenocarcinoma or a villous, serrated, or tubulovillous adenoma of any size or a tubular adenoma greater than or equal to 10 mm.



[http://www.polymedco.com/filebin/images/product\\_images/products.gif](http://www.polymedco.com/filebin/images/product_images/products.gif)

## Test Characteristics with 95% Confidence Intervals

n	Manufacturer	Sensitivity	Specificity	PPV	NPV	LR+	LR-
59	Inverness Clearview	0.43 (.10 to .82)	0.92 (.81 to .98)	0.43 (.10 to .82)	0.92 (.81 to .98)	5.57 (1.56 to 19.88)	0.62 (.32 to 1.18)
447	Alere Clearview	0.25 (.11 to .45)	0.86 (.82 to .89)	0.11 (.05 to .21)	0.95 (.92 to .97)	1.84 (.93 to 3.65)	0.87 (.70 to 1.08)
335	Polymedco OC-Light	0.04 (0.0 to .20)	0.98 (.95 to .99)	0.13 (0.0 to .53)	0.92 (.89 to .95)	1.7 (.22 to 13.28)	0.98 (.91 to 1.06)
77	Quidel QuickVue	0.17 (0.0 to .64)	0.89 (.79 to .95)	0.11 (0.0 to .48)	0.93 (.84 to .98)	1.48 (.22 to 9.94)	0.94 (.65 to 1.36)
918	Total	0.18 (.10 to .29)	0.91 (.89 to .93)	0.14 (.07 to .23)	0.93 (.91 to .95)	2.00 (1.15 to 3.50)	0.90 (.80 to 1.01)

## Materials

- Inverness Clearview Ultra iFOB (n = 61)
- Alere Clearview iFOB Complete (n = 456)
- Polymedco OC-Light iFOB (n = 336)
- Quidel QuickVue iFOB (n = 79)

## Subjects

2,336 subjects were invited, 1,148 consented (49%), and 216 were removed due to ineligibility. This left 932 subjects, of which **918** had valid FIT results. These subjects were used for data analysis.

## Analysis

Exact confidence intervals were calculated for test characteristics that were proportions, and the likelihood ratio confidence intervals were created by the method described in Simel, Samsa, and Matchar (1991). Any invalid FITs (n = 14) were excluded. ANOVA, Pearson chi-square, and Fisher's exact tests (used when chi-square approximation was not appropriate) were used to compare age, gender, histology, and FIT positivity across FIT manufacturers.

## Results

Tests comparing age, gender, and histology by FIT manufacturer were non-significant. In order to explore the non-significance of these tests, estimates of the above variables have been provided in a table below. The test comparing FIT positivity across FIT manufacturer was significant ( $p < .0001$ ), and a follow-up comparing Polymedco positivity to the other three manufacturers collapsed revealed a significant difference ( $p < .0001$ ) as well. As seen by the test characteristics, for those with average risk of colon cancer, the reliability of a one-time, single sample FIT is often low compared with colonoscopy. Longitudinal studies are needed to compare strategies of annual FIT vs. colonoscopy every ten years.

## Sample Descriptives

FIT Manufacturer	Inverness Clearview	Alere Clearview	**Polymedco OC-Light	Quidel QuickVue	Total
*Histology	n = 61	n = 456	n = 336	n = 79	n = 932
Adenocarcinoma, n (%)	0(0)	1(.22)	1(.30)	0(0)	2(.21)
Advanced adenoma and none of the above, n (%)	7(11.48)	27(5.92)	25(7.44)	7(8.86)	66(7.08)
Other adenoma and none of the above, n (%)	17(27.87)	118(25.88)	100(29.76)	18(22.78)	253(27.15)
Other and none of the above, n (%)	37 (60.66)	310 (67.98)	210 (62.50)	54 (68.35)	611 (65.56)
<b>FIT Results</b>					
Positive FITs, n (%)	7(11.48)	64(14.04)	8(2.38)	9(11.39)	88(9.44)
Negative FITs, n (%)	52(85.25)	383(83.99)	327(97.32)	68(86.08)	830(89.06)
Invalid FITs, n (%)	2(3.28)	9(1.97)	1(.30)	2(2.53)	14(1.50)
<b>Gender and Age</b>					
Men, n (%)	30(49.18)	196(42.98)	124(36.90)	35(44.30)	385(41.31)
Mean Age (SD)	55.67 (7.61)	57.72 (7.41)	59.14 (7.40)	56.77 (7.44)	57.93 (7.46)
Women, n (%)	31(50.82)	260(57.02)	212(63.10)	44(55.70)	547(58.69)
Mean Age (SD)	56.97 (6.34)	56.37 (7.55)	56.26 (7.26)	57.55 (7.40)	56.45 (7.35)
Total Mean Age (SD)	56.33 (6.97)	56.95 (7.51)	57.32 (7.43)	57.20 (7.38)	57.06 (7.43)

\*Advanced adenoma = villous, serrated, or tubulovillous, or tubular and  $\geq 10$ mm

Other Adenoma = tubular and  $< 10$ mm

Other = other, no diagnostic abnormality, no histology needed, lymphoid aggregate, or hyperplastic

\*\*Includes Alere samples tested with Polymedco

## References

Simel DL, Samsa GP, Matchar DB. Likelihood ratios with confidence: sample size estimation for diagnostic test studies. *J Clin Epidemiol*1991;44:763-770.