

# ColorectAlertä

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## Comparison of ColorectAlertÖ to fecal occult blood testing and carcinoembryonic antigen for colorectal cancer screening.

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669 individuals scheduled for colonoscopy were enrolled in this study. The population was 53% male, 93% Caucasian and had a mean age of 59 years. 94% of the colonoscopies were completed to the cecum. Fecal occult blood test (FOBT) results were determined from 3 stool samples obtained prior to colonoscopy following the manufacturer's instructions (Beckman Coulter Primary Care Diagnostics, Hemoccult SENZA). Carcinoembryonic antigen (CEA) values (Abbott, AxSYM), determined from serum samples obtained prior to colonoscopy, were positive if >1.0ng/mL. ColorectAlert (CRA) quantitatively determines the presence of D-galactose-β-[1→3]-N-acetyl-D-galactosamine, in a rectal mucus sample obtained during digital rectal examination. Mucus samples were smeared onto CRA membranes and sent to the laboratory for testing. The CRA test results, after treating the membrane-bound mucus samples with galactose oxidase and staining with Schiff's reagent, were quantitated using a hand-held spectrophotometer. CRA results were considered positive if the measured colour after galactose oxidase treatment was >370 and negative if less than 350. Samples with a value of 350-370 were treated with periodate, restained with Schiff's and if the colour value was <350 were also considered positive. Based on colonoscopy and pathological diagnosis of sampled tissue 39% had no bowel pathology, 20% had benign bowel disease, 34% had polyps, and 4% had colorectal cancer. CRA, FOBT, and CEA had similar sensitivity for cancer but CRA was significantly more specific than either FOBT or CEA (p<0.0001). To further improve specificity we constructed algorithms whereby individuals were tested in tandem with the 3 tests. CRA in combination with either CEA or FOBT was more accurate than tandem screening with FOBT and CEA. In this study population CRA was more specific than either FOBT or CEA. CRA could have utility as a colorectal cancer screening test either on its own or in tandem with FOBT or CEA.

Test	Sensitivity*	Specificity**	P-value
CRA	81%	77%	<0.001
FOBT	81%	58%	<0.01
CEA	81%	52%	<0.01
CEA+CRA	69%	90%	<0.001
CEA+FOBT	62%	78%	<0.001
FOBT+CRA	69%	88%	<0.001

\* in colorectal cancer (CRA, CEA n=26; FOBT n=16)

\*\* in patients with no observed bowel pathology (n=262)

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