

ColorectAlert™

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ColorectAlert: A Novel Test for Colorectal Cancer Screening

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Purpose: The purpose of this study was to evaluate ColorectAlert (CRA) as a screening tool for the early detection of colorectal cancer. CRA quantitatively determines the presence of D-galactose- β -[1 \rightarrow 3]-N-acetyl-D-galactosamine (GAG) in a rectal mucus sample. GAG is a carbohydrate moiety that has been found to be associated with adenocarcinomas. CRA makes use of a novel color measurement to quantitate the amount of GAG present in a rectal mucus sample.

Methods: Mucus samples, obtained during digital rectal examination, were smeared onto CRA membranes and sent to the laboratory for testing. The CRA test results were determined by treating the mucus samples with galactose oxidase and then staining with Schiff's reagent. The results were quantitated by determining the color of the developed sample using a hand-held spectrophotometer. The CRA samples were then treated with periodate to oxidise all carbohydrate residues and restained with Schiff's reagent prior to a second color measurement. Test results were considered positive if the measured color (hue angle) was >370 and negative if less than 350. Samples with a value of 350-370 and a value after periodate treatment of <350 were also considered positive. In a prospective clinical trial we compared CRA to fecal occult blood testing (FOBT) for the detection of colorectal cancer in 601 individuals scheduled for colonoscopy. Patients participating in the study provided informed consent. Stool samples from 3 consecutive bowel movements were obtained following the patient instructions for FOBT (Hemoccult SENSE) and a rectal mucus sample was obtained prior to colonoscopy examination. FOBT and CRA testing were done without knowledge of the colonoscopy outcome.

Results: The study population had a mean age of 59 years, was 53% male, and 93% caucasian. 94% of colonoscopies were completed to the cecum or terminal ileum. Based on colonoscopy: 40% of the study population had a normal bowel, 20% had benign bowel disease, 34% had polyps, and 2.7% had cancer. FOBT and CRA were equally sensitive for cancer detection (81.3%, 13/16 cancers) but CRA was significantly more specific than FOBT in this study population (75.1% vs 56.5%, χ^2 $p < 0.001$). The odds ratio associated with a positive CRA test was 13.1 in 5.6 for FOBT. Neither CRA nor FOBT were more likely to be positive in individuals with polyps >1.0 cm.

Conclusion: This novel method, because of its improved specificity, could reduce the cost of screening programs (ie. fewer colonoscopies) without compromising sensitivity.