

 [Print this Page for Your Records](#)[Close Window](#)**Performance characteristics of the OC-Auto Micro 80 for the determination of fecal Occult blood.****Topic:** Cancer/Tumor Markers**R. H. Khoury¹, A. H. Gandhi¹, B. P. Salmon¹, P. Gudaitis¹, D. N. Patel¹, D. Gudaitis¹, P. M. Sluss², A. V. Gudaitis¹.** ¹*Aculabs, Inc., East Brunswick, NJ,* ²*Massachusetts General Hospital, Boston, MA,***Presentation Number:** C-8**Keyword:** FOBT, Occult, CRC

Background: Colorectal cancer is the third most common cancer in the United States and the world. In the USA, it is estimated that 153,270 new cases will be diagnosed and 55,830 deaths by the end of the year 2006. Patients with early detection, localized stage, and appropriate treatment has a 5 years survival rate of 90%; but because early colon cancers rarely display any symptoms the screening becomes a very important tool for improving the survival rate. The American Cancer Society (ACS), US Preventive Service Task Force (USPSTF) and the National Academy of Clinical Biochemistry (NACB) recommend that all subjects 50 years old or older undergo screening for CRC. The most widely used test for screening asymptomatic population is Fecal Occult Blood Test (FOBT), although the test does not decrease the incidence of CRC but it reduces the mortality very significantly. The previous FOBT guaiac test measures the heme in hemoglobin, but because the heme is also present in some fruits and vegetables, consuming these foods may give false positive results. Certain medicine such as non-steroidal anti-inflammatory drugs and vitamin C can interfere with the test. In addition, the need for multiple samples and the unpleasant method of collection make the patient compliance very difficult. The new immunochemical test detects human globulin, and it is not affected by the dietary intact or medicine, as well as being subjected to less interference.

Methodology:

The OC-Auto Micro 80 is an automated immunoassay that detects human hemoglobin using a photometric reading for the presence of an antibody-antigen complex. The instrument measurement from the closed sample collection devices eliminates the exposure of the samples to laboratory personnel. It requires no dietary restrictions and one sample from one stool specimen is needed. The assay is qualitative and the minimum detection limit is set at 100 ng/mL of hemoglobin. We evaluated the assay sensitivity, specificity, and cold recovery, cross reactivity, reliability and correlation with reference lab using OC-Auto.

Results: The assay sensitivity was 100 %; specificity was 100 %, spiked samples were positive, and there was no cross reactivity with any of the substances known to affect the Guaiac method including vitamin C, Iron, and peroxidase. The samples that tested positive were positive over a period of 5 days, and the negative samples were negative over the 5 days testing. The results of 50 samples were identical to the one obtained from different laboratory using OC-Auto and to the existing method.

Conclusion: The Oc-Auto is very sensitive and specific assay and offers several advantages over the guaiac method including better sensitivity and specificity, only one sample needed, easy collection of the specimen; and the major advantage of this assay is decreasing the anxiety for patients and decreasing the number of unnecessary follow-up procedures by decreasing the false positive rate.

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