

January 17, 2017

Christine Muscatell Kaiser Hospital Lab Santa Rosa, CA.

Dear Christine:

I am writing regarding your recent inquiry about using the Hemoccult® or Hemoccult SENSA® tests on "bulk" stool samples (collected into a container).

Beckman Coulter Inc. has no clinical data regarding the use of bulk stool samples. Therefore, according to our Regulatory Affairs Department, we cannot support the use of such samples in our Product Instructions.

In a technical brief, Young, et al state, "Hemoglobin is not stable in stools." They further conclude, "the test cards for fecal occult blood tests based on the pseudoperoxidase activity of heme should be prepared immediately after defecation. Transport of moist samples to the laboratory should be avoided; that procedure results in reduced sensitivity."

Please call hotline at (800) 877-6242 or email <u>askpcd@beckman.com</u> if you have further questions about Hemoccult or Hemoccult SENSA testing.

Sincerely,

Pamela Coltran Senior Customer Technical Specialist Beckman Coulter, Inc 800-877-6242

<sup>1</sup>Young, G.P., et al., "Influence of Delay in Stool Sampling on Fecal Occult Blood Test Sensitivity," *Clinical Chemistry*, 42 (7): 1107-1108, 1996