HiFi DNA Tech, LLC
160 Hawley Lane
Trumbull, CT 06611

Fax 203 385-3832

March 23, 2009

The Honorable Daniel R. Levinson
Inspector General
Office of Inspector General
Department of Health and Human Services
Room 5541 Cohen Building
330 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Mr. Levinson:

Enclosed herewith is a letter that is addressed to the FDA, CDRH, OIVD deputy director, with two supportive documents. Historically, the OIVD director is responsible for approving in vitro commercial medical devices.

HPV test kit manufacturers tend to perform their clinical trials in a population with extremely high cervical cancer prevalence rate and market the developed test kits with FDA approval to direct referrals of patients to colposcopic biopsy cancer work-up in the suburban/rural American female populations with a very low prevalence rate of cervical cancer. The result leads to excessive unnecessary biopsy procedures performed on American women at great cost to the society because the positive predictive value of such test drops dramatically when it is transplanted to the US from a high disease prevalence population to a low prevalence population.

I am trying to ask the FDA to conduct an open scientific panel meeting for this pre-marketing approval. However, the OIVD has a history of ignoring all such requests. I am wondering if your office may intervene on behalf of the American women who live outside of the inner cities, and have one of lowest prevalence rates of cervical cancer in the world.

Respectfully yours,

Sin Hang Lee, MD
Pathologist and
President of HiFi DNA Tech,LLC