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### MORE ON OFFICE-BASED TESTING FOR HIV

*To the Editor:* Recently, Gellert and colleagues expressed strong concern about office-based test systems for HIV, believing that such tests will compromise effective programs of AIDS surveillance and prevention.<sup>1</sup> We question their judgment. As the HIV epidemic continues to rage out of control, it is not clear that current prevention strategies are effective. It is imperative that new approaches be tried — ones that also strive to protect uninfected persons from infection, thereby interrupting the transmission cycle.

Gellert et al. elected to focus on the predictive value of a positive HIV test (office-based), which they estimated to be 50 percent, given a sensitivity of 99.9 percent, a specificity of 99.6 percent, and an HIV prevalence of 0.4 percent in the tested population. By focusing on the harmful effects of misclassification among those who test HIV-positive, Gellert and colleagues overlooked the importance of office-based or home testing for personal decision making by those who want to avoid infection. Using the example of Gellert et al., an uninfected person could have lowered his or her risk of selecting an HIV-infected partner from 0.4 percent without testing to a low of 0.00004 percent among those who test negative — a reduction of 99.9 percent. The reduction would be even greater with confirmatory testing.

As the epidemic increasingly affects heterosexuals, many search desperately for ways to reduce their risk of HIV infection. In addressing the heterosexual spread of HIV, Hearst and Hulley stated that the single most important recommendation for their patients is to avoid choosing a sexual partner who may be at risk of carrying HIV.<sup>2</sup> Because there are no discernible signs or symptoms for an average of 10 years, testing for HIV infection in blood or saliva<sup>3</sup> is the only practical way to detect HIV carriers. Although centers performing both confidential and anonymous testing have been established for this purpose, many heterosexual couples may be reluctant to come to them, out of concern that they might be labeled as homosexuals, drug addicts, or prostitutes. When there are no incentives other than a vague concern about the risk of HIV, the discomfort of taking a blood test or discussing intimate sexual practices may be too much to endure. For such persons, office-based or home HIV-antibody testing would be a welcome alternative as a means of greatly reducing their risk of HIV infection.

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*To the Editor:* The letter by Gellert et al. raises "serious concern about clinical or operational feasibility" with respect to the use of visually interpreted antibody assays to detect HIV infection. Unfortunately, the authors have done their cause a disservice by discussing two unrelated assays in a misleading way. Their letter reveals a fundamental misconception of the basis on which the Food and Drug Administration has granted approval to Fluorognost HIV-1 IFA, the only indirect immunofluorescence assay for HIV antibodies licensed to date.

Fluorognost has been licensed primarily as an additional, more specific test for validation testing in reference centers. As such, it can be used to provide conclusive information on the HIV-antibody status of serum or plasma specimens, whereas the only approved use of the "microfiltration enzyme immunoassay" mentioned is in the primary testing (or screening) of previously uncharacterized specimens. The potential of Fluorognost to resolve "indeterminate" Western blot results has been demonstrated.<sup>1</sup> This fact alone is sufficient to invalidate any direct comparison between these two assays: they belong to entirely different, well-defined categories. An additional licensed use (to screen uncharacterized specimens in physicians' offices, clinics, emergency rooms, and other settings in which enzyme immunoassays are impractical or unavailable) was granted to Fluorognost only because it has been proved to be as sensitive as, but more specific than, standard enzyme immunoassays, on the basis of data from a multicenter trial and a clinical study of 1300 subjects at high risk of acquiring HIV infection.<sup>2</sup> Only 1 false positive result was seen in 10,082 blood donors. The notion that "8 positive results [will result] per 1000 tests, 4 of which are false positive results" is therefore incorrect with respect to Fluorognost.

Furthermore, by stating that "in both assays . . . the interpretation of the assay depends purely on visual skills," the authors imply that visual evaluation is inferior. In doing so, they fail to take into account that tools for the determination of HIV serologic status have always relied exclusively on such evaluation.

On studying the product insert for Fluorognost, Gellert et al. would have found detailed summaries of the extensive clinical studies on which the FDA has based its license.

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The authors reply:

*To the Editor:* We do not agree with the perspective offered by Drs. Frerichs and Seymour on the importance of office-based or home testing for personal decision making in HIV prevention. Because of the latency period between the acquisition of the virus and the appearance of antibody to HIV, this approach to disease control, in which people would conduct tests at home before engaging in sexual relations, offers little real security to the public. People who use the test but persist in high-risk behavior can be incorrectly self-identified as uninfected when in fact they are HIV-positive. Furthermore, given the reality that many people who