September 10, 2002

The Honorable Claude Allen
Deputy Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Mr. Allen:

The undersigned organizations are writing to you with a concern over the possible waiver of regulations for rapid HIV (Human Immunodeficiency Virus) tests.

We believe that a test as critical as HIV screening must be conducted in a controlled and monitored environment, and conducted by trained personnel. Additionally, there is fear that rapid HIV tests, once waived, may be used in hospital and clinical settings. In these settings, there is great potential for immediate pharmacological treatment, due to false test results. The accuracy of rapid HIV tests must be improved prior to the use of these tests in a clinical setting.

The rapid HIV antibody screening test has a lower specificity and sensitivity than Enzyme Linked Immunoabsorbent Assay (ELISA) tests. For example, a specificity of 98% might sound good for a rapid HIV test. Unfortunately, if this test is used by members of a population with a low prevalence of HIV infection, such as normal healthy blood donors, most of the people who get a positive test result are getting a wrong test result.

We understand the desire for patient accessible HIV testing. However, due to the inaccuracy of rapid HIV tests and the implications for both patient and public safety, we respectfully ask that any recommendation for waiver of these tests be denied.

If you have questions or need additional information, please contact any of the organizations below, or call Rachel Judas at (202) 347-4450. Thank you for your attention to this important public health matter.

Sincerely,

American Association of Bioanalysts
American Society for Clinical Laboratory Science
American Medical Association
American Society for Clinical Pathology