



Advancing Excellence

College of American Pathologists

**Statement to the
Food and Drug Administration
Blood Products Advisory Committee
November 3, 2005**

College of American Pathologists

Division of Advocacy

1350 I Street, NW, Suite 590

Washington, DC 20005

(202) 354-7100

(202) 354-7155 – fax

(800) 392-9994

www.cap.org

The College of American Pathologists (CAP) is providing a written response to the notice in the Federal Register regarding the Blood Products Advisory Committee (BPAC) proposed discussion on approaches to over-the-counter (OTC) home-use HIV test kits.

The College of American Pathologists is a national medical specialty society representing more than 16,000 pathologists who practice pathology and laboratory medicine in laboratories worldwide. The College's Commission on Laboratory Accreditation is responsible for accrediting more than 6,000 laboratories here and abroad. College members have extensive expertise in providing and directing laboratory services and serve as inspectors in the accreditation program. In addition, the College provides laboratories with a wide variety of proficiency testing programs and educational solutions to assist in the improvement of the laboratory's performance and its positive impact on patient care. These programs are designed to improve the quality of laboratory services and to ensure the accuracy and reliability of test results. Therefore, the College has a profound interest and extensive experience in this topic.

It is the College's belief that no test is so simple and straightforward to perform that erroneous results cannot occur and that no incorrect test result is "risk free" or inconsequential with regard to potential harm, particularly when testing for HIV. The College believes that all test procedures used for the diagnosis, prevention, treatment and assessment of human disease regardless of designated CLIA test complexity, should be subject to a documented quality control program and to proficiency testing when such is available. With regard to designated CLIA waived tests, we stand in support of the efforts to move forward to develop new and innovative approaches to quality control (QC), proficiency testing (PT), performer competence and test/instrument performance in the field, which will ensure that waived tests are accurate and reliable over the life of the instrument/kit. The College has supported the concept that QC requirements for CLIA designated waived tests be modeled on standard laboratory QC that is devised for laboratory-based methodologies. In this regard, the College is submitting the following comments to the BPAC for consideration.

The College is very concerned with the possibility of allowing tests with significant patient and public health implications, such as HIV testing, to be placed in the home use category. This will allow testing to be performed in unregulated settings that are not subject to appropriate quality control (QC) and proficiency testing. Moreover, the College believes that all HIV testing should include appropriate consent (as required by certain state laws) and counseling procedures, and that all positive HIV test results must be subject to a confirmatory test. These patient safeguards cannot be maintained with a home use HIV test. Furthermore, home use testing will have the potential of limiting public health information reporting on HIV disease prevalence (required in most states). Perhaps more importantly, because home use testing takes place in an unregulated, unmonitored environment and is performed by untrained individuals, a home test, specifically HIV testing, must exceed current industry standards before home testing can be safely provided. On June 14 - 15, 2001, the BPAC met to discuss whether to recommend waived categorization for rapid HIV tests. The BPAC voted against waiving rapid HIV testing from CLIA and advised that rapid HIV tests should meet the CLIA moderately complex criteria and require more studies. Also during the meeting, the BPAC voted in favor of a resolution that would allow the exploration of other approaches under CLIA to promote wider access to rapid HIV testing including the limited public health use category as defined by CLIA regulations. The College supported the position taken by the BPAC. Since that recommendation, the Department of Health and Human Services (HHS) made a decision to approve the rapid HIV test to be designated in the CLIA waived test category. However, the waiver designation sets specific sales restrictions, for example, requiring the manufacturer to verify that the test kit purchaser is a representative of a laboratory. Therefore, while the rapid HIV test is designated in the CLIA waived category, the sales restrictions imposed by the Food and Drug Administration (FDA) are unique for a waived test.

The College recognizes the complexity of the public policy decision on whether to designate HIV rapid testing kits in the home use category under the presumption that more people may have access to such testing. To ensure wider access to quality HIV testing, we would urge the BPAC to consider its previous position on this matter to explore other approaches under CLIA including the current approach by the FDA to restrict rapid HIV testing kit sales to registered laboratories.

In addition, should the decision be made to permit, in principle, licensing of a home-use HIV antibody test, despite the technical and public health concerns, the College recommends that extensive study and evaluation of the particular kit involved, under conditions as closely approximating those of real-world use, be required. Particular specific concerns include:

- The clarity of the interpretive end-point in typical lighting conditions,
- Simplicity of the specimen collection protocol for medically-naive users,
- The behavioral acceptability and impact of incubation times in likely use scenarios.

The College would like to thank the BPAC for the opportunity to present these comments. Please feel free to contact Phil Bongiorno, at (202) 354-7113 or pbongio@cap.org with any comments or questions.