



February 27, 2006

James R. Allen, MD, MPH
Chairman
Blood Products Advisory Committee
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852

Dear Dr. Allen and Blood Products Advisory Committee,

On behalf of the Association of Public Health Laboratories (APHL), I am writing to provide comments to the Blood Products Advisory Committee (BPAC) and Food and Drug Administration (FDA) regarding the criteria and questions that need to be addressed prior to an over-the-counter (OTC) home-use rapid HIV screening test indication is considered. The APHL membership consists of state and local public health laboratories whose primary responsibility is to conduct testing of public health significance for the purposes of surveillance to protect the nation's health. APHL, with a history of over fifty years, is dedicated to working with its members and the health care community in general to strengthen public health laboratories by striving to provide the necessary resources and infrastructure.

The public health laboratories have been on the forefront of HIV diagnostics and testing ever since the discovery of the disease in the early 1980's. Public health laboratories provide screening and supplemental testing for confirmation of HIV for state and local jurisdictions. They were instrumental in assisting the Centers for Disease Control and Prevention (CDC) with developing the current testing algorithm for HIV. APHL also has a position statement on the suggested use of rapid HIV testing in certain settings. The APHL complete position statement can be found at https://www.aphl.org/docs/aphl_hiv_rapid_testing_position_statement_final.pdf.

Rapid HIV testing has been demonstrated to be an effective tool for HIV diagnosis; however, this is only one step in a process that includes counseling, supplemental testing for confirmation, referral into medical care, and access to treatment. APHL is concerned that OTC home-use HIV testing will not provide adequate assurances for these steps, thus negatively impacting the individual patient as well as public health surveillance and control measures.

Currently, there is insufficient data for APHL to either support or oppose the concept of an OTC home-use rapid HIV screening test or any specific test that may eventually seek OTC status. The BPAC meeting held November 3-4, 2005 helped answer some of the questions

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necessary for APHL to consider, however, it brought up several others as well. Studies suggested by the BPAC will be instrumental in providing the required information so that APHL and other organizations can determine their stance on OTC HIV tests. The following questions outline the additional information that APHL will need in order to take an informed position on an OTC home-use rapid HIV screening test.

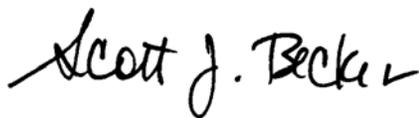
- **How will OraSure Technologies, Inc. ensure that proper quality assurance and proficiency are maintained with an OTC home-use rapid HIV test?** Many states and local jurisdictions that offer the rapid HIV test in their community require counseling and testing sites to undergo extensive training and education prior to these sites administering the test. Will there be any measures contained in the test kit that will ensure that individuals are properly utilizing and interpreting the test? What documents and support will be supplied to ensure that the test is being performed and interpreted correctly?
- **What further analysis and support will be documented to ensure that the product will perform as required after exposure to adverse climate conditions outside the limits as described in the package insert?** Laboratorians are well aware that summer and winter weather can adversely impact the performance of a test kit. Systems are in place to care for the product from the loading dock through use. Are retailers able to provide special handling to protect the test kit? A product that will now go through a secondary transport to the end users home is not controlled for and may impact the result. Therefore, exposures of extreme temperatures and humidity must be validated.
- **What validation studies will OraSure Technologies, Inc. develop in order to assure that the study population mimics that of the general population that will utilize the test?** It is important that studies of test performance conducted by OraSure Technologies, Inc. be done in the population intended to use the test. It is currently not clear what that population is, i.e. who is likely to buy the test - college grads, high school students, homeless people, Medicaid recipients, etc.
- **How will individuals who test reactive or preliminary positive be referred for supplemental confirmatory testing?** The OTC home-use HIV test will act only as a screening tool for HIV infection. Supplemental testing to confirm the presence of HIV antibodies would be required. How does OraSure Technologies, Inc. plan on ensuring that all individuals with reactive or preliminary positive results from the OTC rapid HIV test receive a supplemental confirmatory test?
- **How will OraSure Technologies, Inc. make certain that those individuals who test reactive or preliminary positive are referred into counseling and medical care?** Data provided by Dr. Inungu, Central Michigan University, indicate that discrepancies exist with regards to how a reactive or preliminary positive HIV test result impacts an individual's distress level. With traditional HIV testing, a counselor or physician is on-site to counsel and refer the individual into treatment and care. A supplemental specimen may also be obtained for confirmatory testing during this initial visit. What protocols will be in place to ensure that all individuals receive the same care?

- **What measures will be in place to prevent the bulk sale of an OTC home-use rapid HIV test to entities attempting to establish themselves as a counseling and testing site?** To maintain a high quality of testing, health departments and public health laboratories will want to be able to continue any existing roles in overseeing counseling and testing sites that offer rapid HIV testing. If bulk sales are allowed, then it would circumvent this process.
- **How does OraSure Technologies, Inc. plan on addressing state and local mandates that either require the presence of a physician or do not allow for the sale of rapid HIV tests?** There are some states and local jurisdictions that have these types of requirements. What precautions will be taken to prevent individuals from purchasing an OTC home-use rapid HIV test from another jurisdiction and bringing it over the border?

APHL appreciates the opportunity to react to and weigh in on this very important issue. We realize that an OTC home-use rapid HIV test would allow for many more individuals to be tested for the disease in the United States and potentially seek care. APHL does, however, have concerns and anxiously looks forward to hearing additional information about how OraSure Technologies, Inc. plans to address these issues. The required studies should address many of these concerns, but potential conflicts with established policy or mandates may still exist. The CDC, FDA, and other federal agencies will need to work with APHL and other partners to address these policy issues as well.

Thank you for your time and consideration. If you have any questions or comments, please direct them to Anthony Tran, APHL HIV, STD, TB program manager, at 240-485-2783 or anthony.tran@aphl.org.

Best regards,



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