May 8, 2012

Center for Biologics Evaluation & Research
Food and Drug Administration
1401 Rockville Pike, HFM-71
Rockville, MD 20852

Re: Docket No. FDA-2012-N-0001 – Blood Products Advisory Committee

The Association of Public Health Laboratories (APHL) appreciates the opportunity to provide feedback on the upcoming FDA Blood Products Advisory Committee meeting to discuss the evaluation of the safety and effectiveness of the OraQuick In-Home HIV Test. Although APHL and its members would like to increase access to HIV testing, we are concerned about the performance of the OraQuick In-Home HIV Test in the home setting by untrained users who may not adhere to test instructions, and would like the Advisory Committee to consider the following issues:

- Evidence has demonstrated decreased sensitivity and specificity of rapid HIV tests on oral fluid compared to blood specimens [1,2,3].
- Clusters of increases in false-positive results have been reported with oral fluid using the OraQuick Advance Test [1,4,5,6], stressing that reactive rapid HIV test results are preliminary, regardless of specimen type, and should be confirmed with more advanced test methods [7].
- The lack of assurance that users with positive results will seek appropriate confirmatory testing, counseling and linkage to care. Without the proper counseling and linkage to care, infected individuals may cause further spread of HIV.
- The potential loss of the link to public health systems currently in place to monitor disease and provide partner notifications.
- Untrained users of the in-home device may knowingly or inadvertently stray from the device’s instructions or make “minor” adjustments that they may perceive as insignificant but may affect the results.
- Improper sample collection and handling, device handling and storage, and conformance to written instructions may compromise the quality of test results.
- Rapid tests are not as sensitive as laboratory-based tests on blood specimens for identifying acute HIV infections [8].
• By performing this test at home without the benefit of a health care provider, there is a missed opportunity to discuss with the patient their risk of exposure to other infectious diseases and other testing that could be beneficial.

HIV testing is a critical public health issue. Benefits to an in-home HIV test include increasing testing as it can be performed in the privacy of one’s own home, providing an opportunity to educate more people about HIV, and increasing awareness of the need for medical follow-up. The risks include misuse of the test by untrained individuals in a home setting, failure of the user to understand that reactive results can be false positives and must be confirmed by supplemental testing, and failure of the user to present for counseling and referral to treatment. We believe these risks outweigh the benefits of increasing access to in-home HIV testing.

Sincerely,

Scott J. Becker, MS Executive Director
Association of Public Health Laboratories

APHL represents governmental laboratories that detect and monitor public health threats. APHL’s members include state, territorial, and local public health laboratories; state environmental testing laboratories, state agricultural and food safety laboratories; and individual scientists, public health officials, and academicians.

References:


