Problems with the Fast-Check HIV rapid test kits

Fast-Check HIV-1/2 serum (rapid serum) and Fast-Check HIV-1/2 point-of-care whole blood (POC WB) tests have been marketed in Canada since March 2000. These HIV rapid tests detect IgG antibodies to HIV types 1 and 2. The rapid serum test is intended for laboratory use and the POC WB test is for point-of-care patient testing. In Canadian prelicensing trials involving approximately 950 HIV-positive and 2500 HIV-negative specimens, both tests showed > 99.9% sensitivity and specificity.[1,2] In a feasibility trial, patients and providers preferred the POC WB tests.[3,4] HIV rapid testing in BC was halted on Apr. 10 because of concerns that the kits were not sensitive enough. This letter describes the investigations that form the basis for a nationwide recall of these tests.

In March 2002 the British Columbia Centre for Disease Control (BCCDC) noted performance problems with the rapid serum test, which is used as an additional check on the primary screening enzyme immunoassay. Of the previous 407 known HIV-positive serum specimens, 7 had false-negative results by the rapid serum test, 4 had reactive results by the standard enzyme immunoassay and Western blot (Western blot testing is routinely performed to confirm reactive specimens), and 3 had indeterminate results by the Western blot and positive results by the p24 antigen test, which suggested early seroconversion. After removal of the indeterminate results, the test sensitivity in this analysis was 99.01% (4/404). Repeat testing of these samples on 2 rapid serum test lots showed difficulties in reading the results and lot-to-lot differences in the results. Of grave concern was that the test failed to reliably detect positive Western blot results. This led to the evaluation of the POC WB test using 449 stored sera obtained from subjects in the Vanguard Study (a prospectively tracked population of people at risk of bloodborne infections from whom serum is obtained regularly).[5]

Although the POC WB test is not licensed for serum testing, we were concerned the test might have performance problems because the technical designs of the POC WB and rapid serum tests are similar. In addition, the manufacturer used serum in quality control before release. We therefore tested the 449 serum samples by both rapid serum and standard enzyme immunoassay tests. Of the 303 POC WB test samples, 1 was positive and 302 were negative on all tests. However, of 22 known HIV-positive samples from this cohort that were retested by both the rapid serum and POC WB tests, 20 were positive, 1 was negative on both tests and 1 was discordant on 2 different lots of both the rapid serum and POC WB tests. The poor readability and lot-to-lot variation of the test results were a major concern.

On Apr. 26 the BCCDC issued a public advisory urging people to be retested if they had a negative POC WB test result without subsequent standard enzyme immunoassay testing (see also News, page 180). The BCCDC has since prospectively evaluated the POC WB test from known HIV-positive patients undergoing routine care at St. Paul's Hospital in Vancouver. Ethics approval for this study was obtained from the Institutional Review Board of the University of British Columbia.

As of June 20, 7 of 63 confirmed HIV-positive specimens had nonreactive results by 2 lots, 11 had indeterminate results by 1 or both lots, and 14 others showed faint test results. After removal of the indeterminate results, the sensitivity at this early point was 86.5% (45/52). This is unacceptable for an HIV screening test. Although most of these patients were taking antiretroviral therapy, treatment should not affect test results. No problems were documented in the prelicensing trial that involved over 500 patients taking such treatment.[1,2]

In Canada, 14 191 Fast-Check whole blood and 8425 serum tests have been sold. On the basis of the aforementioned data, Health Canada issued a nationwide safety advisory and the manufacturer stopped selling and shipping both tests on Apr. 29, 2002.[6]

In light of this product recall, we recommend the following:

1. A robust quality assurance program must be in place for point-of-care HIV tests before reinstating Fast-Check whole blood HIV rapid testing in Canada.

2. Anyone with a negative Fast-Check point-of-care test result as his or her last HIV test, especially women who were tested during pregnancy, should be retested using standard enzyme immunoassay screening methods.

3. Fast-Check serum test results should be confirmed.

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