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Competing interests: Dr. Blumer is a coauthor of *Diabetes for Canadians for Dummies* (Wiley & Sons, 2004).

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Final evaluation results for the Fast-Check HIV rapid test kits

In late April 2002, the British Columbia Centre for Disease Control (BCCDC) reported to Health Canada potential problems with the Fast-Check HIV-1/2 point-of-care whole blood (POC WB) test (BioChem ImmunoSystems). On the basis of these data, Health Canada issued a safety advisory,[1] and the test was withdrawn on Apr. 29, 2002.[2] Beginning in the same month, but before the product was withdrawn, the BCCDC began a prospective evaluation of the test in 100 HIV-positive patients undergoing routine care at St. Paul's Hospital in Vancouver, to obtain more systematic data on sensitivity. The study was approved by the Institutional Review Board of the University of British Columbia. In July 2002, we reported results from the first 63 specimens in a letter to *CMAJ*,[3] and this follow-up letter summarizes the results for the entire sample of 100 patients. These data are important because at least one new POC rapid HIV test is now undergoing clinical trials in Canada.[4]

Overall, there were 75 reactive test results (true positives), 12 nonreactive test results (false negatives) and 13 inconclusive results. The sensitivity of the test was 88% (88/100) if inconclusive results are classified as tentatively reactive, 75% (75/100) if inconclusive results are classified as nonreactive and 86% (75/87) if inconclusive results are excluded (Table 1). We believe that, in a clinical situation, inconclusive results would have been classified as tentatively reactive to minimize the number of false negatives and since all positive test results would have been confirmed by another test.

Table 1 shows the test sensitivity for subjects receiving and not receiving treatment, for those with detectable and undetectable viral loads and by CD4 count. There was a trend to higher sensitivity with lower CD4 counts, but this was not statistically significant ($p = 0.37$).

Because this study did not include specimens from HIV-negative subjects, we cannot comment on the specificity of the test; however, classifying inconclusive results as tentatively reactive would likely reduce the specificity.

In summary, the sensitivity of the POC WB test was unacceptable even for untreated patients with detectable viral loads, and the product recall in late April 2002 was the correct move. These results emphasize the necessity of a robust quality assurance program before any new POC rapid HIV test is licensed.

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A question of ethics

A recent *CMAJ* editorial about the outbreak of *Clostridium difficile*-associated diarrhea in certain Canadian hospitals[1] describes the "stifling of concerned voices on the front lines of medicine" as the "worst news" in a bad-

Table 1: Sensitivity of Fast-Check point-of-care whole blood rapid HIV test

Category for inconclusive results	Disease characteristic*; sensitivity of test, %										
	Overall	Patient undergoing treatment			Detectable viral load			CD4 count†			
		Yes	No	*p*	Yes	No	*p*	< 200	200–500	> 500	*p*
Reactive	88 (88/100)	86 (69/80)	93 (14/15)	0.68	89 (48/54)	79 (22/28)	0.32	84 (16/19)	89 (42/47)	76 (13/17)	0.37
Nonreactive	75 (75/100)	72 (58/80)	80 (12/15)	0.75	72 (39/54)	68 (19/28)	0.46	79 (15/19)	74 (35/47)	53 (9/17)	0.20
Excluded	86 (75/87)	84 (58/69)	92 (12/13)	0.68	87 (39/45)	75 (18/24)	0.32	83 (15/18)	88 (35/40)	69 (9/13)	0.29

*The total number of subjects within each disease characteristic is less than 100 because data were missing for some patients for some characteristics.
†Fisher's 2-sided exact test.