



12 July 2012

Dear Members

RE: Recall of SD Bioline tests

Yesterday, there were media reports about the National Department of Health recalling the SD Bioline HIV 1 2 testing kits. While the validation of the test had been done at the NICD, reports of a high number of invalid tests were received. Apparently, there were few if any false results. However, the quality concerns have resulted in a recall of the tests.

In terms of the algorithm for HIV testing, all positive tests must be confirmed with a second test kit. At the moment, many clinics are using the SD Bioline test as the screening test and the Abbott Determine as a confirmatory test.

We would advise the following

- Use the Abbott Determine or your current confirmatory test as the screening test
- IF the test is positive, then confirm with a second test. The National Department of Health has provided the First Response HIV test as the confirmatory test, in the affected province
- If your facility does not have sufficient stock of the First Response HIV test, please send us an email at stockouts@sahivsoc.org or SMS us at 087 042 2001.

Please re-assure all those who come for testing, that the tests that are now in use are validated. We need to ensure that the public confidence in the testing procedure is restored as soon as possible.

Sincerely

A handwritten signature in black ink, appearing to read "Francesca Conradie".

Dr Francesca Conradie
President: Southern African HIV Clinicians Society