

# Market alert

## Reducing risk in the global supply of HIV test kits

Recent events in the HIV test kit market have reminded us of the significant risks all testing programs face. The test kit market has been dominated by three HIV diagnostic tests: Determine (about 75 percent for PFSCM shipments the last three years), Uni-Gold (about 11 percent), and Bioline (about 9 percent).

WHO and USAID have removed SD Bioline HIV kits from their waiver lists due to quality assurance problems until further notice. As a result, many global HIV/AIDS programs are working quickly to determine how to replace SD Bioline in their testing algorithms. But this is not the first indication of a problem with a market dominated by three products. In March, 2011 Alere, the manufacturer of Determine kits, experienced temporary electrical brownouts and labor shortages due to the earthquake in northern Japan; *all* Determine test kits are manufactured in one facility. Had the manufacturing plant sustained serious damage, the global supply of HIV test kits would have been severely strained.

As countries consider revisions to testing protocols as a result of the removal of Bioline from waiver lists, they may want to **consider widening the number of test kits** purchased to help create a more sustainable market.

Providing a wider range of options in testing protocols will result in increased purchases from a larger number of suppliers. By increasing the number of suppliers who receive regular orders from HIV/AIDS programs, we can create a healthier market that is better able to respond to shocks like the ones we have recently seen.

Programs should seek clinical advice from trusted advisors when considering changes to their testing algorithms. For a complete list of approved test kits, go to the waiver lists found on-line at USAID ([www.usaid.gov](http://www.usaid.gov)) and WHO ([www.who.int](http://www.who.int)).

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