

## HIV testing on the cheap

Researchers have identified a less expensive test than the commercially available assays used to assess disease progression and response to antiretroviral therapy among HIV-infected individuals a recent report claims (*J Infect Dis* 2002; **186**: 1181–85). The new assay, called heat-denatured HIV-1 protein (p24) antigen, costs US\$20–30, and is easier to store and transport than the conventional assays.

“The test”, Timothy Sterling (Johns Hopkins Bloomberg School of Public Health, MD, USA), lead author, told *TLID*, “could be used to determine when to initiate antiretroviral therapy in HIV-infected persons and may be of particular benefit in [HIV/AIDS-hit] resource-poor countries”. N Kumarasamy (YRG Centre for AIDS Research and Education, Chennai, India) agrees, but suggests more prospective studies that could determine the “efficacy” of p24 antigens. Currently, it costs more than \$1000 per year to monitor a patient on antiretroviral therapy, a figure that is simply too high for developing countries to afford (*Lancet Infect Dis* 2002; **2**: 656–57).

At baseline, the researchers quantified levels of p24 antigen in plasma obtained from 494 adult injection drug users with early-stage HIV-1 infection. 97% of participants were African Americans. Baseline p24 antigen levels were closely correlated with CD4+ cell count and serum HIV-1 RNA. 90 of 494 participants developed AIDS within 5 years. A p24 concentration of 5 pg/mL and CD4 lymphocyte count of 350 cells/ $\mu$ L, or a viral load of 30 000 copies/mL were comparable in predicting progression to AIDS. Susan Fiscus (University of North Carolina, Chapel Hill, NC, USA) considers the results very important because they provide information on the use of p24 antigen among non-whites. “Because of previous data with the standard p24 antigen assay there has been some concern that the heat-denatured p24 assay would also prove less sensitive in specimens from non-Caucasians. These data suggest that this may not be a problem.”

However, Fiscus cautions: “Large studies of non-subtype B specimens have not yet been performed and it will be necessary to evaluate the utility of this assay in other countries”. WHO’s Jos Perriens believes that the findings “would open an avenue for the assessment of risk of disease progression in areas where viral load cannot easily be determined”. However, he points out that waiting for laboratories to be able to determine CD4 cell counts would

unduly delay treatment access for hundreds of thousands of people, in spite of the fact that several technologies exist that allow determination of a CD4 cell count for less than \$10 per analysis. “For the same reason, WHO recommended [in April this year] that the determination of viral loads should not be a priority for antiretroviral treatment programmes in developing countries”, Perriens continued.

**Khabir Ahmad**

## Most US hospitals avoid reuse of single-use devices

About 25% of hospitals in the USA reprocess single-use devices (SUDs), according to the results of a telephone survey by the US Food and Drug Administration (FDA). Of the hospitals reusing SUDs, 84% use third-party reprocessors to sterilise these devices.



Using SUDs just the once.

“We were encouraged to see that hospitals were not taking on this burden in-house, because we do think it is a significant burden to comply with all the regulations”, Nancy Pressly (Office of Surveillance and Biometrics, Center for Devices and Radiological Health, FDA, Rockville, MD, USA) told *TLID*.

Since the August 2000 FDA enforcement of regulatory requirements for reprocessed SUDs, US hospitals have three options for managing reprocessed SUDs: (1) reprocess internally and become the manufacturer of the SUD, (2) use a third-party reprocessor, or (3) decide to avoid SUD reuse. “Roughly 75% choose the third option, which is they are avoiding the reuse of single-use

devices—that is surprising to me”, William A Rutala (Department of Medicine, University of North Carolina, Chapel Hill, NC, USA) told *TLID*.

Between December 2001 and February 2002, the FDA surveyed all for-profit, non-profit, and government hospitals, except Veterans Administration and Department of Defence hospitals. The response rate for the survey was 79.1%. Rutala would have expected more hospitals to choose third-party reprocessors and wondered if the hospital representative answering the survey had accurate information. “Unless there is some type of institutional-wide requirement to report reuse to a risk management or to an infection control committee, it may be sent out for third-party reprocessing by department, without institutional awareness”, he says.

Almost half of all large hospitals (greater than 250 beds, which represents 20% of all US hospitals) report reuse of SUDs, whereas only slightly more than one-tenth of small hospitals (less than 50 beds, 27% of all US hospitals) report reuse. The FDA will use the survey findings to help develop educational and enforcement strategies with hospitals.

A list of the most commonly reused SUDs, according to the FDA’s executive summary can be found at <http://www.fda.gov/cdrh/Reuse/survey-execsum.html>

**Mary Quirk**