AUSTRALASIAN ASSOCIATION OF CLINICAL BIOHEMISTS INC

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**To:** Professor Chris Baggoley, Dr Tony Hobbs

**From**: AACB PoCT National Committee

**Date:** 6th May 2014

**Re:** **"views on a proposal to allow the registration and sale of in vitro diagnostic devices (IVDs) for self- testing (home testing) for the presence of human immunodeficiency virus (HIV)"**

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As a stakeholder you have invited us to comment on the proposal and in particular:

- **The risks and benefits of home testing as a means to enable and promote timely HIV detection and increase testing rates overall, particularly amongst hard- to-reach population groups.**

Overall the committee envisage a greater benefit than risk to the wider community due to regulation of an IVD test that is readily available "online".

## Risks

- A patient receiving a false negative result i.e. sensitivity of device not sufficient to prevent false negative results in early positive patients (window period);
- A patient not following up a positive result, instead choosing to ignore the result;
- A patient reacting negatively to a positive result or a false positive result;
- Other testing normally carried out at the time of HIV testing would not be performed and hence other infectious diseases may remain undiagnosed e.g. syphilis, gonorrhoea and chlamydia testing;
- Use of a device with insufficient test performance i.e low sensitivity and/or specificity;
- QC not interpreted correctly;
- Incorrect use of the test, no training;
- Incorrect interpretation of the test device result;
- Risk of performance of test due to mishandling of the IVD.

## Benefits

- A regulated approach to at home HIV testing (privacy);
- Support for patients receiving a positive result if a hotline 24/7 service is established;
- Availability of the test that can be easily repeated;
- Community awareness and self -responsibility of HIV as disease threat;
- Patients with little accessibility to medical services will be able to access testing and hence treatment sooner;
- Increase early detection amongst all at risk population groups.

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**The risks and benefits of allowing TGA to approve such devices for HIV self- testing that are of acceptable safety and quality and perform as intended to increase HIV detection rates in Australia**

## Risks

- Non TGA approved devices may be extrapolated as approved and hence utilised by individuals;
- Ongoing monitoring of devices available may not be sufficient to prevent individuals accessing non- regulated devices;
- Inability to ensure recall of devices if necessary;
- No training can be ensured;
- No assured checks can be made to check that the device is performing in situ as expected.

## Benefits

- Regulation of a device that is becoming prominent ;
- Improved surveillance by TGA of a growth market in HIV IVD self- testing devices;
- Improved support for new positive patients through government counselling;
- Recall of device if insufficiency is detected.

**Any limitations or conditions that should be placed on the supply of HIV self- testing devices.**

## Limitations and conditions

- TGA to be transparent online with all testing and evaluation of kits to be used, both with pretesting data and post marketing surveillance;
- Funding should be available/provided for a hotline supplying 24 hour counselling to patients requiring assistance with a positive result;
- A large colourful sticker should be provided on the outside of the HIV test package clearly indicating a hotline number to be called if a positive result is received;
- The hotline should also be available for instructions on use, checking the device, interpretation of the result and counselling on a negative result;
- All instructions for use of the device must be clearly written with the end user in mind and available in all languages;
- Diagrams should be included to ensure that a positive, negative and invalid result is clearly demonstrated pictorially (and realistically);
- Packaging should clearly indicate “repeat this test if (potential) exposure has been less than 3 weeks”. This should ensure that the “window” period is covered. N.B. The number of weeks needs debate to arrive at the optimum number for the kit chosen as seroconversion may take up to 10 weeks;
- Purchase of product from pharmacy only, to enable counselling by a professional at the point of sale.

The committee agrees in principle to the proposal.

**Rosy Tirimacco**
Chair
AACB PoCT Committee

**Noelene Wilson**
Microbiology Representative
AACB PoCT Committee