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## **AMA submission – TGA performance requirements for HIV point-of-care tests and self-tests**

**[devicereforms@tga.gov.au](mailto:devicereforms@tga.gov.au)**

The AMA supports the proposed performance requirements and risk mitigation strategies for HIV point-of-care tests and self-tests outlined in the consultation paper released by the TGA in November 2014.

In particular, the AMA fully supports the proposed mitigation strategies in relation to self-tests. As raised in previous submissions, it is essential that self-testers understand the limitations of these tests, the importance of seeking medical practitioner advice to confirm positive results, and how to contact counselling and support services.

It is also important that manufacturers also clearly include on labels and product information the likely risk of false positive and false negative results for both point-of-care tests and self-tests.

The AMA understand that the current National HIV Testing Strategy is being updated to address issues associated with HIV self-testing and to support national and state level HIV strategies. Without this updated strategy and the broader context it would provide, it is difficult to make further comment about the likely effectiveness of the TGA's proposals.

**JANUARY 2015**

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