Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

HIV point-of-care tests: Conditions of approval for supply in Australia

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All tests for the detection of HIV (https://www.tga.gov.au/node/289330), or human immunodeficiency virus, are in vitro diagnostic (IVD) devices, which must be approved by the TGA and included in the Australian Register of Therapeutic Goods (ARTG) to be legally supplied in Australia. The following conditions apply specifically to HIV point-of-care tests (PoCT), which are screening tests intended to be used by trained healthcare professionals in clinical settings, near the patient. A positive result from a PoCT must be confirmed by laboratory testing.

1. The person (the sponsor) in relation to whom the '[IVD medical device]' (the Device) is included in the Australian Register of Therapeutic Goods (the ARTG) must ensure that the Device is only supplied for use by:
    a. laboratories that are accredited by the National Association of Testing Authorities (NATA) as medical testing laboratories and that participate in an HIV point of care quality assurance program; or
    b. organisations that:
        i. employ healthcare workers who will perform, or supervise the performance of, HIV testing using the device; and have received training in the delivery and administration of HIV testing in accordance with the requirements of the National HIV Testing Policy; and
        ii. have an established relationship (in relation to the referral and testing of specimens) with a NATA accredited medical testing laboratory; and
        iii. participate in an HIV point of care quality assurance program.
2. The sponsor of the '[IVD medical device]' must make available training in the correct use of the Device and interpretation of results.
3. The sponsor must maintain records that demonstrate that the device has been supplied in compliance with condition 1 and that it has complied with condition 2.
4. The sponsor must provide to the Therapeutic Goods Administration (TGA) a post market surveillance report for each reporting period commencing on the date of inclusion of the device in the ARTG and ending at the end of the next 30 June and each twelve (12) months

thereafter for the next five (5) financial years. Reports must be provided to the TGA before 1 October after each reporting period and must include the following:

a. Numbers of tests sold in Australia and Worldwide.

b. Any adverse events including numbers of any reported false positive or false negative results in Australia and Worldwide.

c. Reported problems or complaints associated with the use/interpretation of the device in Australia and Worldwide.

5. Post-market reports must be sent to the TGA at the following email address postmarketdevices@health.gov.au.