

16 June 2025

Proposed Changes to the IVD Classification Rules and Principles

Thank you for the opportunity to provide feedback on the '*proposed changes to the IVD medical device classifications and definitions*' document. Public Pathology Australia (PPA) is generally supportive of the proposed changes and provides the following comments.

It must be clarified whether the proposed changes also impact Human Papilloma Virus Nucleic Acid Testing (HPV NAT). This testing methodology falls under additional National Pathology Accreditation Advisory Council (NPAAC) regulatory requirements. The overlay of assay specific NPAAC rules will potentially create additional complexities when combined with the Therapeutic Goods Administration (TGA) classification. It is not just about having the assay approved, but the specifics of the approval. For instance, with many molecular tests the assay may be approved for (1) one specific specimen type, collected from (2) only limited sites, in a (3) specific container type and in a (4) specific manner (e.g. clinician collect vs self-collect). When you put these four variables together it can be quite limited as to what the manufacturer has TGA registration for. This then falls back on the laboratory to validate if the test is required for clinical diagnostics. These validations can be quite difficult due to availability of clinical specimens and determination of a gold standard, and in some instances can take years to complete a validation.

PPA's primary concern with the changes concerns the potential impact on the availability and cost of reagents and instruments in the Australian market. Suppliers of products designated to higher classifications may not be prepared to meet the classification changes to ensure their products remain on the Australian Register of Therapeutic Goods (ARTG). Pathology providers in Australia already experience difficulties as some products are unavailable as the return from the Australian market does not warrant suppliers undertaking additional work to meet the requirements for ARTG registration. The proposed amendments to IVD classifications could potentially worsen this problem. In Australia, the pathology sector has already seen a loss of assays due to suppliers deciding to remove them from the Australian market, with difficulties finding replacements e.g. Treponema Pallidum Particle Agglutination (TPPA) test for syphilis. This drives up costs and resourcing in terms of having to find alternatives, perform verifications, potentially purchase new equipment, manage IT changes and determining new workflows. With TPPA, there was a critical cut-off date for supply, yet even a couple of months prior to that there was no TGA registered alternative. The assay which most laboratories had anticipated would be the replacement (and for which verification studies had been performed) did not secure TGA approval, so there were last minute scrambles after waiting to see if another option would secure approval.

The proposed changes for laboratory instruments may be more problematic unless grandfathering is introduced. If laboratories have invested in a large and expensive piece of equipment and then the company decides it does not want to obtain TGA approval, it will further limit the spectrum of testing that can be done on that item of equipment. This will then be more difficult and expensive for laboratories to change to an approved platform. The MALDI-TOF instrument used for bacterial identification is one such example. There are only two different suppliers in Australia. Validation requires companies to assess a large spectrum of microorganisms. If they need to re-register as class 3 rather than class 1 it may increase costs and limit the performance by reducing the less common organisms in the database. **PPA recommends an individual assessment of mass spectrophotometer instruments for bacterial identification** as this equipment is used in conjunction with other tests for the identification of bacteria.

Whilst laboratories can liaise with manufacturers about expectations and progress, often there can be last minute decisions to not bother with the requirements and withdraw the assay. This leaves laboratories vulnerable with a risk they may not have much ability to control.

If there is a potential impact to the availability of testing reagents and/or instruments, the **TGA must consider the impact to pathology service delivery prior to making changes** to mitigate loss of testing capability within the Australian pathology industry.

In summary, the potential impacts to the Australian pathology sector from an increase in regulatory requirements include:

- (i) loss of assays from the market
- (ii) increasing costs of assays directly
- (iii) indirect cost for the laboratory in performing verification and validation studies, introducing new assays, IT infrastructure and changing workflows/staffing demands due to changes in TGA registration/potential loss of some assays
- (iv) restriction of use of assays due to limitations on specimen type, site, container types and collection methods
- (v) service impacts and infrastructure cost with the changes associated with large and expensive platforms.

These risks and impacts could potentially be mitigated by alignment to European Union regulations where the manufacturers already have data and re-submit to the TGA; and the proposed phase in period.

PPA is fully supportive of the proposed classification and definition changes with no impact on approved IVDs.

I agree to this submission being published without my name and contact details but including PPA's name. [REDACTED]

Yours faithfully
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