

Proposed Performance Requirements and Risk Mitigation Strategies for HIV Tests

The proposed model accepts that HIV PoCT and Self Tests may be considered fit for purpose if the risks associated with using the test are mitigated and the benefits from use of the test outweigh the risks.

1. This approach does not seem to be in evidence elsewhere in the regulation of pathology tests. Instead regulation is imposed based on perceived risk alone, an example being the In Vitro Diagnostic Device (IVDD) scheme. For consistency, were the proposed model for HIV testing adopted, it is recommended that it be adopted across pathology testing generally. This would have some benefits. For example it would provide a framework to manage the currently vexed issue of class IV IVDD for rare exotic pathogens such as smallpox. Here the absence of cases or clinical samples renders impossible the extensive test validation that is an absolute requirement for a class IV IVDD, while no alternatives exist in the form of commercial tests, and yet availability of test capacity is an absolute public health necessity.

2. Since the validity of the model hinges on benefit outweighing risk some attempt to quantify both benefit and risk is recommended. Currently the proposal contains only qualitative assertions. If the model is adopted then data quantifying both expected risks and benefits should be collected post implementation, and subsequently analysed to compare the actual risk/benefit outcome with that expected.

3. For both PoCT and Self Tests the model proposes that the sponsor report to TGA the numbers of false negatives. It is not clear how false negatives will be detected, and the document is silent on this. Since no further testing occurs after a negative result there is no opportunity to confirm its veracity. Real time parallel testing with a reference test would be required to detect a false negative. Parallel testing won't be happening for either PoCT or Self Tests as it obviates the point of these strategies: greater penetration of testing into the community than is currently possible with existing laboratory based tests and testing infrastructure. Equally unlikely is retrospective detection of false negatives via investigation triggered by a subsequent positive result. Original specimens from PoCT and Self Test settings will not be available for such retrospective evaluation. False negatives are an important risk in HIV testing, and the proposed mitigation does not appear to be robust.