TGA Consultation: Review of the regulation of certain self-testing IVDs in Australia

Feedback from Communicable Diseases Branch

Consultation question	**Feedback**
Considering the experience with HIV self-testing should self-tests for other infectious diseases be supplied and used in Australia subject to appropriate risk mitigations?	
Are there any tests for particular infectious diseases that should not be available as a self-test? Please provide reasons why not.	Access to self-testing for respiratory viruses such as influenza and RSV could have a positive public health benefit if advice on actions to take based on the results is focussed on both the clinical care of the person and measures to reduce further transmission Self-testing for controlled notifiable diseases (e.g. measles) that are highly transmissible should not be available. The disease can result in severe disease and may result in missed notifications to public health authorities and subsequent increased risk of further community transmission. The risks and benefits of self-testing kits for each infectious disease should be undertaken by experts in infectious diseases and public health prior to approval.
Do you have any additional suggestions on how potential risks to consumers could be mitigated if self-tests for other infectious diseases were allowed to be supplied in Australia?	Only make available self-test kits with high sensitivity and specificity Require the supplier to include clear instructions on follow-up actions when tests are positive or negative Ensure the instructions are appropriate to the Australian health system
Other comments	If regulation of certain self-testing in vitro diagnostic medical devices (IVD) in Australia is changed, this may result in a reduction of public health surveillance information unless guidelines exist requiring testing at an accredited laboratory if medical treatment is required. If, for example, a patient is able to test for an STI at home; unless testing is also performed by an accredited diagnostic laboratory, from where isolates and samples are referred for public health surveillance, information regarding circulating strains, in particular multi-drug resistance will not be captured. This information is crucial in public health response and informs guidelines for treatment. Another example is testing at home for strep throat; which

	unless tested by an accredited laboratory will not have antimicrobial resistance data, which can affect antibiotic choice for treatment, surveillance data and information for development of antibiotic stewardship guidelines for medical services such as GPs and hospitals. If there is a mechanism for ensuring appropriate supplementary testing following at home testing, this will mitigate the above risk to our public health surveillance. **Additional information** The discussion paper deals with “routine” infectious diseases such as influenza and hepatitis C. Forensic and Scientific Services deals with “specialised notifiable” infectious diseases such as measles, dengue and norovirus. Self-test IVDs are not, and should not, be available for these diseases because contact persons need to be notified in the event of a positive notifiable disease. The Excluded Purposes Specification must be revised to specify that specialised notifiable infectious diseases are excluded.