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To Whom It May Concern,

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

The comments regarding the review of the regulation of certain self-testing in vitro diagnostic medical devices (IVDs) in Australia are on behalf of the Communicable Disease Control Branch (CDCB), Department of Health and Wellbeing, SA Health. Only tests relating to infectious diseases and notifiable conditions were reviewed, as genetic testing and other diseases are not currently relevant to CDCB.

In principal the CDCB is in favour of lifting exclusions on self-testing IVDs for infectious/notifiable conditions, provided they meet the same specifications the currently available HIV self-test had to meet to mitigate the risks associated with self-tests. We see the potential benefit of more accessible and earlier and testings, and the potential for earlier intervention, outweighs the risks provided they meet the criteria of having high sensitivity/specificity, are clear and easy to use, have advice on interpreting the result and what to do with the result, and have support services available.

It is also worth mentioning that there are added logistical issues relating to notifications from positive self-tests which may be an issue for health departments and timely public health action. We have experienced at least one situation at the CDCB where we were notified of a positive HIV result from a HIV self-test (confirmatory testing was done via a laboratory in South Australia) that was complicated by an alias name being used and the support service being based in the United Kingdom, making it difficult for CDCB staff to contact this service due to time zone differences. This caused some delay until the correct identity of the case was able to be established. This has the potential to delay appropriate public health action and ensuring these cases are linked to care. Some of this delay may have been reduced by having a support service based in Australia, or at least in the same time zone.

Thank you for the opportunity to comment on this review.

Regards,

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COMMUNICABLE DISEASE CONTROL BRANCH

18/11/2019