FOR IMMEDIATE RELEASE

HEALTH SCIENCES AUTHORITY
PRESS RELEASE
5 JUNE 2017

HSA ALERT: RECALL OF SD BIOLINE HIV Ag/Ab COMBO ASSAY

The Health Sciences Authority (HSA) has overseen the recall of nine lots of SD BIOLINE HIV Ag/Ab Combo assay due to issues of reduced sensitivity of its HIV screening test, which could result in false negative HIV results for some persons who were tested during the early stages of an HIV infection.

2 HSA was notified by the local importer, Unison Collaborative, that nine lots of SD BIOLINE HIV Ag/Ab Combo assay were recalled by the product owner, Standard Diagnostics, Inc. (SD). The recall was due to the reduced sensitivity of nine lots of SD Bioline HIV Ag/Ab Combo Assay test kits which could result in false negative HIV results for individuals who were tested during the early stages of an HIV infection. According to the manufacturer, when a patient is in the very early window period, the lower sensitivity of the affected lots may reduce detection, with the possibility of a false negative result for this subset of patients.

3 Unison Collaborative issued an urgent Field Safety Notice (FSN)[1] on 11 May 2017 to 26 clinics and one hospital which were supplied with the affected lots of these test kits. Users were advised to stop using the affected kits and to retest individuals who had tested negative using the affected lots.

4 As a precautionary measure, all 36 healthcare facilities supplied with SD Bioline HIV Ag/Ab Combo assay test kits had been directed by HSA to stop using the test kits and to use other alternative rapid HIV test kits until further notice. Clinics and hospital have also been advised to review the HIV test results of all individuals tested using the affected lots and to perform re-tests as necessary.

Consumer advisory

5 The following persons with high risk of HIV exposure who have taken a rapid HIV test between February 2016 and May 2017 are advised to check with their clinic on the need for a re-test:

(i) Tested negative for HIV infection at the clinics listed on **Annex A** between February 2016 and May 2017; AND
(ii) Did not return as advised for a re-test more than 3 months after the last exposure.

6 Healthcare providers routinely advise persons with high risk of HIV exposure who tested negative for HIV infection using any brand of rapid HIV test kits to return

[1] FSN is a safety communication used by HSA through the importer of a medical device to inform end-users of device-related concerns and the remedial actions to take.

for another test more than 3 months after their last exposure to confirm that they are HIV negative. This is to rule out early infections that might not have been picked up at the first screening.

7 Alternative brands of HIV test kits are available. There is no disruption to the offer of these services to persons who would like to test their HIV status. Individuals seeking rapid HIV testing services may continue to be tested at all existing 99 medical clinics across Singapore. For further clarification, please contact HSA at Tel: 68661048.

About the test kit

8 There is a window period of up to three months during the early stages of HIV infection when blood tests may be unable to detect the infection. The SD Bioline HIV Ag/Ab Combo Assay is a rapid HIV Antigen and Antibody combo test, which shortens the window period, and enables healthcare facilities to screen for HIV infection earlier. All rapid HIV tests are intended to be used only as an initial screening test, and are not meant to confirm HIV infection. Positive rapid test results must be confirmed by sending a blood specimen to a clinical laboratory for Enzyme Immunoassay (EIA) testing and further confirmatory testing by Western Blot if necessary.

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About the Health Sciences Authority (HSA)
The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

For more updates on public health and safety matters, follow us on Twitter at www.twitter.com/HSAsg.

About HSA's Health Products Regulation Group
The Health Products Regulation Group (HPRG) of HSA ensures that drugs, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

ANNEX A

HSA ALERT: RECALL OF SD BIOLINE HIV Ag/Ab COMBO ASSAY

List of Clinics/Hospital Supplied with affected and recalled lots of SD Bioline HIV Ag/Ab Combo Assay test kits

1. Action for AIDS*
2. Balestier Clinic and Health
3. Doctors Clinic & Surgery*
4. Dr Jeremy Chan Medical Clinic
5. Dr Soh's Family Clinic*
6. Elyon Family Clinic and Surgery
7. iCare Medical @ Wellness Clinic
8. Island Family Clinic Keat Hong Pte Ltd
9. Island Family Clinic (Seng Kang)
10. Kensington Family Clinic*
11. M Lam Clinic*
12. National University Hospital (NUH)
13. Nuffield Medical Siglap Pte Ltd
14. O2 Medical Clinic
15. Pinnacle Family Clinic
16. Platinum Family Clinic
17. Prudence Family Clinic
18. Q & M Medical (Tampines)*
19. Q Medical Clinic Pte Ltd
20. Republic Clinics (Dr Tan & Partners)
21. Sagemed Pte Ltd
22. Shim Clinic
23. Silver Cross Medical
24. SMG Dermatology Centre
25. Tanjong Pagar Medical Clinics*
26. Vienna Medical Clinic
27. Zenith Medical Clinic

*Anonymous HIV Test sites