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**HEALTH SCIENCES AUTHORITY
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HSA Committee Completes Review and Releases Recommendations

Re-testing of 87 DNA Cases Completed: Results Consistent with Initial Scientific Assessment

On 3 January 2012, the Health Sciences Authority (HSA) announced that it had initiated the re-testing of DNA samples in 87 ongoing criminal cases as a precautionary measure, in consultation with the Singapore Police Force (SPF), the Central Narcotics Bureau (CNB) and the Attorney-General's Chambers (AGC). The re-testing was initiated following HSA's discovery that a reagent of higher than usual concentration ("the Reagent") had been prepared and used as part of the DNA testing process in the DNA Profiling Laboratory (DNAPL) in HSA, from October 2010 to August 2011. HSA had estimated that additional reportable DNA profiles may be obtained in fewer than 5% of the samples.

2. HSA has completed the re-testing in the 87 cases. The results are consistent with the initial assessment of the scientific impact of using the Reagent. Additional reportable DNA profiles were obtained in 2.9% of the samples re-tested (65 out of a total of 2,194 samples). All 65 profiles were previously detected in the samples but in amounts below the reportable level. Of these, seven profiles were not previously reported.

3. The DNA re-test reports have been submitted to the SPF and the CNB. The AGC will be assessing all available evidence, including the re-test results, in arriving at the appropriate prosecutorial decision in each case.

4. The HSA Board Review Committee set up on 1 January 2012 to review the incident has also completed its work. The Review Committee was chaired by Ms Serene Wee, CEO Singapore Academy of Law and Chairman, HSA Audit Committee. The other members of the Review Committee were Professor Ranga Krishnan, Dean of Duke-NUS Graduate Medical School and Board member of HSA, and an independent member, Mr Max Loh, Country Managing Partner, Ernst & Young Singapore & ASEAN Managing Partner, Ernst & Young.

FINDINGS AND RECOMMENDATIONS OF THE REVIEW COMMITTEE

Assessment of the Incident

5. The Review Committee noted the Laboratory Manager made an error when preparing the Reagent. Under the then prevailing Standard Operating Procedure, there was no separate process of verifying the composition of the preparation. While a validation performance check was done on the Reagent following international laboratory protocols, the decreased sensitivity of the test was not evident.

6. The Review Committee noted that DNAPL had taken prompt actions to discontinue the use of the Reagent and to assess its scientific impact in consultation with external experts. There was active communication and continual engagement by HSA with its stakeholders. HSA adopted an open and transparent approach in informing the public of the incident.

7. The Review Committee noted that the number of samples received for testing by the DNAPL has increased within the last few years, without a corresponding increase in manpower. While there is no evidence to suggest that the increase in workload contributed to the error, it does present potential stress on the laboratory.

Key Recommendations

8. The Review Committee has made the following recommendations:

- i. No further action be taken against the Laboratory Manager beyond the letter of warning that had been issued by HSA management, in view of the commendable action by the Laboratory Manager to report the error promptly;
- ii. There should be clearly defined protocols for the preparation of reagents including checks on the preparation process;
- iii. The staffing needs for the DNAPL should be reviewed and addressed in light of its current and anticipated workload;
- iv. The risk management framework for DNAPL should be further strengthened in its systems and processes for error prevention, identification, timely reporting and rectification. HSA should also consider establishing a technical audit committee. The DNAPL should continue with the five-yearly accreditation by the American Society of Crime Laboratory Directors Laboratory Accreditation Board (ASCLD/LAB)¹ and annual internal audit in order to continue holding itself to international standards and best practices.

¹ ASCLD/LAB is a United States based accrediting body for forensic laboratories. It is the largest accrediting body for forensic laboratories in the world.

HSA's Response

9. Following the discovery of the incident, HSA had taken actions to strengthen the processes in the DNAPL. It has introduced tighter procedural checks on the reagent preparation process. DNAPL now purchases commercially-prepared reagents, where available. Any other reagent preparation is done under additional direct supervision.

10. HSA agrees with the key observations and accepts the recommendations of the Review Committee. In implementing these recommendations, HSA will continue to enhance its quality improvement and risk management framework to build in even more robust systems and processes in the DNAPL and other laboratories. HSA will work with the HSA Board to set up a Technical Audit Committee comprising relevant external experts to provide guidance on DNAPL and other Laboratories.

11. Professor John Wong, Chairman of the HSA Board said "The Board accepts the findings and recommendations of the Review Committee. They have provided a comprehensive review on the Incident and made recommendations that will enable the DNAPL to enhance its processes further. I am heartened to note the Review Committee's assessment that the staff displayed commendable professionalism with self reporting, transparency and immediate steps to rectify the error. This is reflective of the integrity that we place so much value on within the organisation."

13. HSA's Chief Executive Officer, Associate Professor John Lim said "HSA, as a scientific authority, regards the robustness of our testing responsibilities as critical. Ensuring public trust in our test results and decisions is paramount. The incident has provided us with important learning points to strengthen our laboratory processes and procedures across the organisation. We have implemented and will continue to introduce necessary measures to prevent a recurrence and further enhance our laboratory processes."

HEALTH SCIENCES AUTHORITY

▪ 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, 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. It operates the national blood bank, Bloodbank@HSA, securing the nation's 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/>.