<u>HA announcement regarding a product</u> <u>recall by a laboratory equipment</u> <u>supplier</u>

The following is issued on behalf of the Hospital Authority:

The Hospital Authority (HA) spokesperson today (11 December) announced the response of public hospitals towards a multi-country product recall by a laboratory equipment supplier.

The HA was informed by Abbott Laboratory on 5 December the risk of potentially falsely elevated or false positive results arising from some batches of Abbott Architect Reaction Vessels, a consumable used in various assays.

An urgent ad hoc meeting with all hospital clusters was held last Friday (6 December) with relevant the clinical and laboratory representatives. Public hospitals have immediately switched to other unaffected batches, while laboratories concerned have initially reviewed the impact of the potentially deviated results, upon identifying all types of tests involved.

The vessels of the affected batches are used at HA hospitals for various haematological, biochemical and microbiological tests since late 2018.

"Preliminary assessments suggest that it is improbable patients were materially harmed as a direct result, nor does there seem to be any imminent, immediate and critical patient harm," the HA spokesperson said.

"Repeat tests will usually be performed to reconfirm positive results for treatment considerations, while clinicians will also consider other test results and clinical signs and symptoms for elevated readings in making diagnosis."

"The incident should have no impact on safety of blood or organ recipients because only samples with negative test results would be used," the spokesperson added.

Meanwhile, the HA has met with representatives from Abbott Laboratory to express its concerns regarding the handling of the product recall, to urgently request further definitive information on the cause and magnitude of potential deviation, together with recommendations for remediation. Information on the response of overseas health authorities are being gathered through the supplier. All HA laboratory teams will further review the patient data with the most up-to-date supplier information to reaffirm the clinical impact and, if needed, patients concerned will be contacted directly for further follow up. The HA will continue to monitor the latest development of the incident for necessary follow up actions.