Hospital Authority proactively follows up with supplier on prostate specific antigen reagent product recall

The following is issued on behalf of the Hospital Authority:

The Hospital Authority (HA) spokesperson made the following announcement today (June 3) regarding a product recall of a prostate-specific antigen (PSA) reagent by medical device supplier:

The HA is proactively following up with medical device supplier Abbott Laboratories Limited on a PSA reagent product recall event. On May 27, the HA received notification from the supplier about complaints received in different places, revealing quality issues with certain batches of a PSA reagent. These issues have led to deviations in test results, with some readings exhibiting positive bias greater than 10 per cent, which could potentially lead to a misdiagnosis of prostate cancer, causing doctors to erroneously consider unnecessary treatments.

The HA attaches great importance to the event. Upon receiving notification from the supplier, a thorough review was conducted across public hospitals, confirming two affected batches of reagent (Alinity i Total PSA Reagent Kit – Lot Numbers: 71210FZ00 and 71213FZ00) were delivered to Caritas Medical Centre (CMC) and Tuen Mun Hospital (TMH) respectively.

The CMC has started to use the affected batch of reagent to test 406 patient blood samples since April 28. For prudence's sake, CMC has reviewed the test results and will contact approximately 70 patients this week, based on their clinical needs to rearrange blood tests. The remaining patients have also been scheduled for follow-up appointments in the coming weeks, during which doctors will explain the event and arrange appropriate management to ensure their treatment unaffected.

The HA spokesperson stated, "A PSA test is not a standalone diagnostic indicator. Doctors will make a comprehensive clinical judgment based on patient's clinical condition and other examinations, such as a rectal examination, an ultrasound scan and a biopsy examination to diagnose whether the patient has prostate cancer. The CMC has confirmed that no patients have undergone unnecessary clinical procedures nor experienced delays in treatment due to the event. CMC has set up a hotline, 5334 0388 for patient enquiries (office hours: Monday to Friday, 9 am to 5 pm, excluding public holidays)."

For the reagent delivered to TMH, they have not yet been put into use, and no patients have been affected. CMC and TMH have stopped using the affected batches of reagent and replaced with alternatives. The HA has also reviewed the reagent used in other public hospitals and confirmed that none have used the affected batches. The PSA testing service in all public

hospitals remain unaffected.

A spokesperson stated, "The HA is following up on this event stringently and has notified the Department of Health (DH). We have demanded the supplier concerned to thoroughly investigate its quality control and testing records, provide an explanation, and implement remedial measures. The HA does not rule out taking further action to hold the supplier accountable."

The HA will continue to closely follow up with the DH and the supplier. The supplier will be required to provide quality control records and testing certifications in the future to prove that their testing supplies meet with the stringent requirements so as to ascertain patient safety and testing accuracy.