Hospital Authority announces laboratory test product incident

The following is issued on behalf of the Hospital Authority:

The spokesperson for the Hospital Authority (HA) today (December 9) announced a laboratory test product incident:

The HA received notification from medical device manufacturer bio Merieux that two batches of varicella zoster virus test kits may give false positive results due to invalid calibration. As a result, the tests may not give accurate results on immunity against varicella zoster virus, which causes chickenpox.

Upon receiving the notification, the HA immediately suspended use of the batches of test kits concerned, and switched to other batches. The affected blood samples were also traced.

Tuen Mun Hospital (TMH), Hong Kong Children's Hospital (HKCH) and Kowloon West Cluster (KWC) had used the batches of test kits concerned, involving 411 people. TMH and HKCH repeated the tests for all 249 blood samples and the results were consistent. Among the 162 samples in KWC, 11 were from patients. Nine patients have been arranged to return to hospital to repeat the test, while the other two patients have had other confirmatory tests and retesting would not be needed. The remaining 151 samples belong to hospital staff, performed for recruitment body checking and post-exposure contact tracing. The hospital will contact them to repeat the tests accordingly. If indicated, chickenpox vaccination will be arranged for the staff according to infection control protocols.

The HA is concerned about the incident and will continue to follow up with the product manufacturer. The HA will also liaise closely with the Department of Health on the latest developments.