Updates on recall of blood test reagent and blood products

The following is issued on behalf of the Hospital Authority:

Regarding an earlier announcement on a blood test reagent and blood products recall arrangement, the spokesperson for the Hospital Authority (HA) gave the following update today (June 5):

After receiving notification from reagent manufacturer Bio-Rad, the HA earlier announced the recall of two batches of a blood test reagent and related blood products, as the reagent might give a false-negative result during the red blood cell anti-mia antibodies screening test. Hospital blood banks and the Hong Kong Red Cross Blood Transfusion Service (BTS) have completed reviewing blood samples tested by the concerned reagent. The results are as follows.

The BTS has traced and reviewed 4 594 blood samples tested by the reagent concerned, among which four specimens were confirmed as having false-negative results. The blood in these specimens had been processed to six bags of blood products, including two bags of red blood cells and four bags of platelets, and had been distributed to hospitals. Two bags of unused red blood cells were recalled immediately, while the four bags of platelets sent to Tseung Kwan O Hospital (TKOH), Queen Mary Hospital (QMH), Gleneagles Hong Kong Hospital and Hong Kong Baptist Hospital have already been transfused to patients. Upon reviewing clinical records and retesting, the patient who received transfusion in QMH does not have the corresponding antigen, while the patient at TKOH is known to have the corresponding antibodies. Hence, transfusion of the concerned platelet would not affect the two patients' clinical condition. The BTS has notified the doctors of the private hospitals to follow up on the condition of the other two transfused patients.

In addition, all 17 hospital blood banks have reviewed the type and screen results of a total of 3 860 blood samples tested by the concerned reagent. It was confirmed that no patient has been transfused with inappropriate blood products, but 10 patients' tests showed false-negative results. Hospitals have accordingly updated three of the concerned patients' medical records. The other seven patients' medical records are not affected as they had received the test before and had the results properly recorded in their medical records.

The HA is very concerned about the incident and has taken serious action to follow up with the reagent manufacturer. The HA has also requested the manufacturer to implement remedial measures and to avoid occurrence of the incident in future. The BTS and hospital blood banks have already switched to other batches of reagent or reagent provided by other manufacturers. The HA's blood test services remain as normal.

The HA has notified the Department of Health the result and appropriate follow up action.