

Government continues to monitor private laboratories to keep up quality assurance standards

A Government spokesman said today (September 2) that the Government will continue to closely monitor the performance of private laboratories to ensure early testing and detection of COVID-19 in accordance with the Government's overall anti-epidemic strategy.

In light of a few incidents in late-January to April this year involving a government contractor for COVID-19 testing service, BGI, the Government invited the Hong Kong Quality Assurance Agency (HKQAA) to conduct a third-party audit on the private laboratory concerned in late-April, with a view to improving the quality assurance management of the laboratory concerned as well as enhancing the overall monitoring of other private laboratories.

The HKQAA reviewed relevant documents of the private laboratory concerned (including standard operating procedures), with reference to the applicable international standards as benchmarks. On-site observation and staff interviews were also carried out to evaluate if the laboratory concerned had implemented the procedures as documented. Recommendations resulting from the study are as follows:

- to ensure proper management of the laboratory in areas such as the formal organisational structure and standardised procedures in daily operations, incident management and reporting;
- to implement preventive measures, such as more stringent control on the testing environment of the laboratory to reduce the risk of contamination;
- to put in place corrective measures, such as establishing proper procedures for laboratory staff to detect, report and follow up on laboratory incidents; and
- to continue to follow up on all the recommendations made by experts based on past incidents.

The private laboratory concerned has responded positively to the study, and has taken immediate follow-up action as shown in the Annex. In view of the positive responses of the private laboratory concerned and the follow-up and improvement actions carried out, the Government will allow the laboratory, as one of the nine community testing centre (CTC) operators, to resume operating mobile specimen collection stations with effect from September this year when necessary.

The Government has also shared the recommendations of the study with the other eight CTC operators for reference, so as to ensure proper delivery of

COVID-19 testing services to the public.

The Government has all along been adopting measures to enhance the quality of the testing services provided by private laboratories to the public, including reviewing and extending the service provided by 18 CTCs and increasing the number of operators, as well as further tightening the accreditation standard of the list of "Local COVID-19 nucleic acid testing institutions recognised by the Hong Kong SAR Government" maintained by the Department of Health.

The Food and Health Bureau expressed gratitude to the HKQAA for agreeing to take on this study, and providing insightful observations during the process.