

Government enhances monitoring on testing ability of private medical testing institutions

The Department of Health (DH) today (December 7) said that it has enhanced its monitoring on the services provided by and the testing ability of private medical testing institutions carrying out COVID-19 nucleic acid tests, and the list of "Local COVID-19 RT-PCR testing institutions recognised by the Hong Kong SAR Government" (recognised testing institutions) has also been updated in view of the testing property of the Omicron mutant strain.

According to information from the World Health Organization, the Omicron mutant strain possesses multiple spike protein gene mutations, and the spike protein gene targets may not be detected if the testing institution uses a particular and single polymerase chain reaction-based nucleic acid (PCR) testing kit. In view of the relevant information, the DH's Public Health Laboratory Services Branch (PHLSB) took the initiative to understand whether the testing kits being used by the recognised testing institutions in Hong Kong are affected.

Investigations revealed that according to the information provided by a manufacturer, Applied DNA Sciences, one of its commercial testing kits "The Linea COVID-19 v1.0 kit" detects two targets at the spike protein gene. The possibility of a discrepancy could not be ruled out when conducting tests against the Omicron mutant strain, thus resulting in "false negative" results. "The Linea COVID-19 v1.0 kit" has been the only testing kit used by Medtimes Molecular Laboratory Limited.

A spokesman for the DH explained that there are currently over 50 COVID-19 nucleic acid testing kits being used in the local market. With regard to the property of the Omicron mutant strain, if the testing institution adopts testing kits detecting more than one target other than the spike protein gene to test samples carrying the Omicron mutant strain, the chance of having a discrepancy can be largely reduced.

Taking into consideration the situations of Medtimes Molecular Laboratory Limited, the DH has adopted prudent measures by temporarily removing Medtimes Molecular Laboratory Limited from the list of recognised testing institutions until Medtimes Molecular Laboratory Limited has introduced other testing kits with their testing ability verified by the DH. The DH has also advised Medtimes Molecular Laboratory Limited to acquire other testing kits to replace the current one for accurately testing against the Omicron mutant strain that may exist.

Medtimes Molecular Laboratory Limited is actively contacting those clients who have used its testing services in the past two weeks and is arranging re-tests at another recognised testing institution. Medtimes Molecular Laboratory Limited has also set up a hotline for related enquiries

(3575 9766).

"Under the current strategy of 'guarding against the importation of cases', the Omicron mutant strain may most probably exist only in samples of inbound travellers. Medtimes Molecular Laboratory Limited has not provided testing services for the Temporary Specimen Collection Centre at Hong Kong International Airport, the quarantine centre nor designated quarantine hotels. Its clients are mainly individual organisations or members of the public in the local setting. As there is no Omicron case detected in the local community so far and the relevant testing kit will not affect the ability of detecting other mutant strains, we believe that the impact of such findings on the overall testing ability of Hong Kong will be minimal," the spokesman reiterated.

The medical testing institutions currently on the list have all fulfilled the requirement of the External Quality Assessment Programme for COVID-19 testing of the DH and possess relevant laboratory accreditation. The DH has verified that the other medical testing institutions on the list have been using testing kits detecting targets other than the spike protein genes. The DH's PHLSB will continue to monitor the standard of COVID-19 testing services of medical testing institutions and conduct external quality assessments regularly to ensure their testing quality.

The updated list has been uploaded to the "COVID-19 Thematic Website" (www.coronavirus.gov.hk/pdf/List_of_recognised_laboratories RTPCR.pdf) for viewing.