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COVID-19 Point of Care Test Kits

Media release

22 April 2020

From today only approved point of care test kits for COVID-19 will be able to be imported and sold in New Zealand.

Medsafe is today banning the importation and sale of all point of care COVID-19 test kits, unless they gain approval. No point of care test for COVID-19 has so far been approved.

Medsafe acknowledges that internationally there has been a lot of work done in developing point of care testing, but believes that more development is required to produce a reliable point of care test.

In particular, Medsafe has concerns about both the quality of testing from many of these kits and the likely impact of misinterpreted results.

Notification was published in the New Zealand Gazette (https://gazette.govt.nz/notice/id/2020-go1737) that prohibits the importation, manufacture, packing, sale, supply, or use of COVID-19 point of care test kits that have not been otherwise authorised by Medsafe.

This action was taken using the provisions in section 37 of the Medicines Act 1981 (http://www.legislation.govt.nz/act/public/1981/0118/latest/DLM55445.html).

It does not affect the test kits currently being used by the Ministry of Health for COVID-19 testing.

It has been taken in the interests of public safety and to ensure that only test kits that are of an appropriate quality and used in circumstances where the results can be interpreted effectively are available for use.

As quality of the kits improves, it is expected that we would get to a point where a point of care test could be approved for use in New Zealand.

Medsafe's approach is supported by the Ministry's Chief Science Advisor and Chair of the Covid-19 Technical Advisory Group, Dr Ian Town, and the NZ Point of Care Testing Advisory group.

Additional Information

The text of the gazette notice is as follows:

Pursuant to section 37 of the Medicines Act 1981, the Minister of Health hereby prohibits the importation, manufacture, packing, sale, supply or use of any kits and/or other test materials intended for use as point of care testing for COVID-19 infection or for post-infection confirmation using an antigen or antibody detection system unless the particular test kit and/or test materials:

(a) has been approved by the Group Manager, Medsafe, Ministry of Health, and
(b) the kits and/or test materials are imported, manufactured, packed, sold, supplied with the intention that they are only to be used for testing by a specified category of registered health care professional approved by the Group Manager, Medsafe, Ministry of Health.

This notice does not apply to kits and/or other test materials imported by or supplied to the Institute of Environmental Science and Research, or a designated alternate entity approved by the Group Manager, Medsafe, Ministry of Health.

Note: This notice is valid for one year from the date of publication of this notice.

Test kits

There are two primary types of COVID-19 test kits.

The PCR one that is used by the Ministry of Health and that takes a tissue sample which is then se away to a laboratory for positive identification of the SARS-CoV-2 virus.

A second test that can be used in the home or workplace, sometimes called point of care testing which uses a blood sample to detect antibodies in the blood. There is concern internationally about the accuracy of the blood sample point of care testing kits and the potential for them to be misinterpreted or provide a misleading result.

Media contact

Peter Abernethy
021 366 111 (tel:021366111)

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