

Revocation and Replacement Authorisation of Persons to Import, Supply, Sell, Distribute, and Use Certain Molecular Point-of-Care Tests Under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021

Pursuant to clause 8 of the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 (“Order”), I, Dr Ashley Bloomfield, the Director-General of Health, being satisfied that:

- a. the activities authorised in this notice will not pose a material risk to the public health response to COVID-19; and
- b. the authorisation is not inconsistent with the purpose of the Act; and
- c. the authorisation is no broader than is reasonably necessary to address the matters giving rise to it.

authorise the persons and classes of persons listed in Schedule 1 of this notice to import, supply, sell, distribute or use the molecular point of care test devices listed in Schedule 2 of this notice.

Schedule 1: Persons Authorised Under This Notice

Persons and classes of persons authorised under this notice are:

- a. All laboratories accredited by International Accreditation New Zealand (IANZ) to ISO 15189 for COVID-19 testing.
- b. All District Health Boards established by section 19 of the New Zealand Public Health and Disability Act 2000.
- c. All hospitals certified under the Health and Disability Services (Safety) Act 2001 to provide hospital care, as defined in section 4 of that Act.
- d. New Zealand Clinical Research (NZCR).
- e. Medical suppliers and distributors importing tests listed in Schedule 2 for the sole purpose of supply, sale or distribution of the tests directly to District Health Boards or an IANZ ISO 15189 accredited laboratory.
- f. New Zealand Defence Force (NZDF).

Schedule 2: Tests Permitted to be Imported, Supplied, Sold, Distributed or Used by Authorised Persons

Point-of-care molecular test
Product name: GeneXpert Manufacturer: Cepheid
Product name: Cobas Liat Manufacturer: Roche
Product name: ID Now Manufacturer: Abbott
Product name: Biofire FilmArray Manufacturer: MediRay
Product name: VitaPCR Manufacturer: Credo Diagnostics
Product name: SAMBA II SARS-CoV-2 Test, SAMBA II SARS-CoV-2/RSV Test and SAMBA II SARS-CoV-2/FluA/FluB Test Manufacturer: Diagnostics for the Real World

Note: This notice revokes and replaces “Revocation and Replacement Authorisation of Persons to Import, Supply, Sell, Distribute, and Use Certain Molecular Point-of-Care Tests Under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021” published in the [New Zealand Gazette, 2 June 2022, Notice No. 2022-go2190](#).

Dated at Wellington this 8th day of July 2022.

DR ASHLEY BLOOMFIELD, Director-General of Health.