Revocation and Replacement of Authorisation of Persons to Import, Supply and Distribute 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, the Director-General of Health, authorised the following persons or class of persons to import, supply, distribute, sell to other authorised persons or classes of persons, and use approved point of care rapid antigen tests:

- All laboratories accredited by International Accreditation New Zealand (IANZ) to ISO 15189 for COVID-19 testing and who provides laboratory testing services to District Health Boards
- All New Zealand Public Health Units and District Health Boards
- All New Zealand Public Sector (as defined by the Public Service Commission)
- All New Zealand-based businesses with a registered New Zealand Business Number (NZBN) including non-government organisations (NGO)
- The entire healthcare workforce including hospitals, public and private health providers, Māori health providers, general practices, and aged residential care
- All local authorities – regional councils and territorial authorities (city and district councils).

The above persons or classes of persons are authorised to import, supply, distribute, sell, or use approved point of care rapid antigen tests for the Public Health Response or business health and safety.

The above persons or classes of persons are **not** authorised to import, supply, or use the point of care rapid antigen tests for their private or personal use.

The following point of care rapid antigen tests are approved for import and use in New Zealand:

Product name(s): SARS-CoV-2 Rapid Antigen Test (SD Biosensor) **Manufacturer (country):** SD Biosensor (Republic of Korea) **Sample type(s):** Nasal, nasopharyngeal, or oropharyngeal swab **Product configuration:** Professional or self-test of any package size
Product name(s): PanBio COVID-19 Ag Rapid **Manufacturer (country):** Abbott Rapid Diagnostics Jena GmbH (Germany) **Sample type(s):** Nasal, nasopharyngeal, or oropharyngeal swab **Product configuration:** Professional or self-test of any package size
Product name(s): CareStart COVID-19 Antigen **Manufacturer (country):** Access Bio Inc (United States of America) **Sample type(s):** Nasal, nasopharyngeal, or oropharyngeal swab **Product configuration:** Professional or self-test of any package size
Product name(s): Atomo COVID-19 Antigen Test **Manufacturer (country):** Access Bio Inc (United States of America) **Sample type(s):** Nasal, nasopharyngeal, or oropharyngeal swab **Configuration:** Professional or self-test of any package size
Product name(s): CLINITEST Rapid COVID-19 Antigen Test **Manufacturer(s) (country):** Healgen Scientific Limited Liability Company (United States of America) *or* Zhejiang Orient Gene Biotech Co., Ltd (China) **Sample type(s):** Nasal, nasopharyngeal, or oropharyngeal swab **Configuration:** Professional or self-test of any package size

Product name(s): Healgen Rapid COVID-19 Antigen Test and Orient Gene Rapid COVID-19 Antigen Test **Manufacturer(s) (country):** Healgen Scientific Limited Liability Company (United States of America) *or* Zhejiang Orient Gene Biotech Co., Ltd (China) **Sample type(s):** Nasal, nasopharyngeal, or oropharyngeal swab **Configuration:** Professional or self-test of any package size
Product name(s): BD Veritor System for Rapid Detection of SARS-CoV-2 and BD kit for rapid detection of SARS-CoV-2 (visually read) **Manufacturer (country):** Becton, Dickinson and Company (United States of America) **Sample type(s):** Nasal swab **Configuration:** Professional or self-test of any package size
Product name(s): Sofia SARS Antigen FIA Test kit with Sofia and Sofia 2 analyser **Manufacturer(s) (country):** Quidel Corporation (United States of America) *or* Puritan Medical Products Company LLC (United States of America) **Sample type(s):** Nasal swab **Configuration:** Professional or self-test of any package size
Product name(s): Ecotest COVID-19 Antigen Nasal Test Kit **Manufacturer (country):** Assure Tech (Hangzhou) Co Ltd (China) **Sample type(s):** Nasal swab or nasal pen **Configuration:** Professional or self-test of any package size
Product name(s): STANDARD Q COVID-19 Ag Test and STANDARD i-Q COVID-19 Ag Home Test **Manufacturer (country):** SD Biosensor (Republic of Korea) **Sample type(s):** Nasal, nasopharyngeal, or oropharyngeal swab **Configuration:** Professional or self-test of any package size
Product name(s): GenBody COVID-19 Ag Test **Manufacturer (country):** GenBody Inc. (Republic of Korea) **Sample type(s):** Nasal, nasopharyngeal, or oropharyngeal swab **Configuration:** Professional or self-test of any package size

Dated this 3rd day of February 2022.

DR ASHLEY BLOOMFIELD, Director-General of Health, Ministry of Health.

Note: This notice revokes and replaces "Amendment to the Notice of Expansion to Authorisation of Persons to Import, Supply and Distribute Point-of-care Tests Under the Public Health Response (Point-of-care Tests) 2021" published in the *New Zealand Gazette*, 28 January 2022, Notice No. 2022-go283; "Notice of Expansion to the Authorisation of Persons to Import, Supply and Distribute Point-of-care Tests Under the Public Health Response (Point-of-care Tests) 2021" published in the *New Zealand Gazette*, 25 January 2022, Notice No. 2022-go235; "Notice of Authorisation for Expanding Import, Supply and Distribution Under the COVID-19 Public Health Response (Point-of-care Tests) Order" published in the *New Zealand Gazette*, 21 January 2022, Notice No. 2022-go201.

2022-go340 04-02-2022 09:17