Full Exemption of Certain COVID-19 Point-of-care Tests Under the COVID-19 Public Health Response (Point-of-care Tests) Order 2021

Pursuant to Clause 9 of the COVID-19 Public Health Response (Point-of-care Tests) Order 2021 ("Order"), I Dr Ashley Bloomfield, Director-General of Health, exempt the point-of-care rapid antigen tests listed in Schedule 1 from all prohibitions under clause 7 of the Order.

The effect of this exemption is that any person may import, manufacture, supply, sell, pack, or use the exempted point-of-care rapid antigen tests specified in Schedule 1 without restriction under the Order.

Schedule 1: Point-of-care Tests Exempt From Clause 7 Restrictions

Product name(s): Roche SARS-CoV-2 Rapid Antigen Test (SD Biosensor) **Manufacturer (country):** SD Biosensor (South 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 (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 at Wellington this 24th day of February 2022.

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

Note: This notice revokes and replaces "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" published in the *New Zealand Gazette*, 4 February 2022, Notice No. 2022-go340.

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