



InnovationScientific

UNDERTAKING

We, _____, understand the conditions as specified by TGA below for the use and supply of the InnoScreen Covid-19 Rapid Antigen test kits. We acknowledge and accept that the kits are for professional use only and must not be supplied for the purpose of self-testing. The kit will be sold/used within Australia as per the TGA guidelines outlined below.

- (a) a laboratory that is an accredited pathology laboratory within the meaning of the *Health Insurance Act 1973*;
- (b) a medical practitioner, or an organisation, business or institution that employs or engages a medical practitioner, registered to practice under a law of a state or territory, where the practitioner is responsible for performing or supervising the performance of the test, and both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the Device and interpretation of the test result;
- (c) a residential care or aged care facility that employs or engages a health practitioner, within the meaning of the *Therapeutic Goods Act 1989*, where the practitioner is responsible for performing or supervising the performance of the test, and both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the Device and interpretation of the test result;
- (d) an organisation, business or institution that does not have the primary function of providing healthcare services but employs or engages a health practitioner within the meaning of the *Therapeutic Goods Act 1989*, where the practitioner is responsible for performing or supervising the performance of the test, where both the practitioner and a person acting under the practitioner's supervision to perform the test have received training in the correct use of the Device and interpretation of the test result;
- (e) a department of the Commonwealth, state or territory, with responsibility for health, or a department or other agency of the Commonwealth, state or territory acting on its behalf.

For detailed condition from TGA, please refer to <https://www.tga.gov.au/applying-tga-assessment-covid-19-test-inclusion-artg#conditions>

We also acknowledge we will undertake all necessary training from the supplier prior to using the product.

Authorized Signatory

Print Name:

Company:

Date:

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