Abbott

Qualification for Supply of Point of Care COVID-19 Ag or Ab In Vitro Diagnostic Medical Devices

The Therapeutic Goods Administration (TGA) has restricted the supply of point of care COVID-19 antigen IVDs:

(Applying for TGA assessment of a COVID-19 test for inclusion in the ARTG | Therapeutic Goods Administration (TGA) and Q&As - Conditions of supply for rapid antigen tests | Therapeutic Goods Administration (TGA))

and the WA Government has given directions relating COVID-19 testing and other health requirements (COVID-19 coronavirus: Health (www.wa.gov.au)).

This form is to ascertain whether your entity can satisfy these conditions, allowing the supply of the Panbio COVID-19 Ag Rapid Test Device, and your entity's use of the Panbio COVID-19 Ag Rapid Test Device will be in compliance with the WA Government's directions.

1. **Date**

2. **Name of company / business / government department**

3. **Customer Type - the products will be supplied to:**

☐ Accredited pathology laboratory (Now please answer Q4 and Q8 only, then sign the form)

☐ A medical practitioner who is registered under a law of a state or territory to practice medicine, a person registered under a law of a state or territory to practice paramedicine (a paramedic), or an organisation, business or institution that employs or engages a medical practitioner or a paramedic, where:

I. the medical practitioner or the paramedic is responsible for performing or supervising the performance of the test; and

II. the device is only used to test employees or contractors of the organisation, business or institution; or a patient under the direct care of the medical practitioner or the paramedic.

(Now please answer Q5 and Q8 only, then sign the form)

☐ A residential care or aged care facility, or a home care service provider, that employs or engages a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the health professions listed below (Please mark the person's profession), where:

I. this person is responsible for performing or supervising the performance of the test; and

II. the device is only used to test residents, employees or contractors of, or visitors to, the residential care or aged care facility, or clients, employees, or contractors of the home care service provider.

a) Aboriginal and Torres Strait Islander health practice ☐;
b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist) ☐;
c) medical ☐;
d) medical radiation practice ☐;
e) nursing ☐;
f) midwifery ☐;
g) occupational therapy ☐;
h) optometry ☐;
i) paramedicine (a paramedic) ☐;
j) pharmacy ☐;
k) physiotherapy ☐;
l) podiatry ☐;
m) psychology ☐.

(Now please answer Q5, Q6 and Q8 only, then sign the form)

☐ An organisation, business or institution that employs or engages a person who, under a law of a State or internal Territory, is registered or licensed to practice in any of the health professions listed below (Please mark the person's profession), where:

I. this person is responsible for performing or supervising the performance of the test; and

II. the device is only used to test employees, contractors or students of the organisation, business or institution, or a person who is a patient of a practitioner registered under a law of the state or territory to practice dentistry and who requires an emergency dental procedure.

a) Aboriginal and Torres Strait Islander health practice ☐;
b) dental (not including the professions of dental therapist, dental hygienist, dental prosthetist or oral health therapist) ☐;

c) medical ☐;
d) medical radiation practice ☐;
e) nursing ☐;
f) midwifery ☐;
g) occupational therapy ☐;
h) optometry ☐;
i) paramedicine (a paramedic) ☐;
j) pharmacy ☐;
k) physiotherapy ☐;
l) podiatry ☐;
m) psychology ☐.

(Now please answer Q5 and Q8 only, then sign the form)

☐ A department of the Commonwealth, State or Territory, with responsibility for health (Now please answer Q8 only, then sign the form)

☐ A department or other agency of the Commonwealth, State or Territory acting on the behalf of a department of the Commonwealth, State or Territory, with responsibility for health. (Now please answer Q7 and Q8 only, then sign the form)

4. NATA accreditation and RCPA ID

NATA Accreditation No.

RCPA ID No.

5. Medical practitioner / health practitioner / paramedic responsible for performing or supervising the performance of the testing

Full Name:
AHPRA registration number:
Email:
Phone No.:

6. **Type of facility?**

- ☐ Aged care facility
- ☐ Residential facility (ie disability and/or rehabilitation facility)
- ☐ Home care service

7. **Acceptable agency of department of health**

☐ We are included in the list of Australian government departments and agencies and have been appointed /contracted to acquire COVID-19 test kits on behalf of a Commonwealth, State or Territory department of health.

8. **The Panbio COVID-19 Ag Rapid Test Device will be used in accordance with the directions given by the Western Australian Government relating to COVID-19 testing and other health requirements, as set out on the Western Australian Government website (**COVID-19 coronavirus: Health (www.wa.gov.au)**)?**

- ☐ Yes
- ☐ No

Signature of authorised person:

Name:

Position:

Email:

Phone Number:

Please email the completed, signed form to both ABBOT Diagnostic and EBOS Healthcare
rapiddx.ANZ.quality@abbott.com
regulatory@ebosgroup.com.au

Please note, as per the TGA conditions, training must be undertaken prior to commencing any testing.