OnSite®
COVID-19 Antigen Rapid Test

Qualification for Supply of Point of Care COVID-19 Antigen In Vitro Diagnostic Medical Devices

The Therapeutic Goods Administration (TGA) has restricted the supply of point of care COVID-19 antigen IVDs. This form is to ascertain whether your entity can satisfy these conditions, allowing the supply of the OnSite COVID-19 Ag Rapid Test Device

For more details see the TGA Website:

- Applying for TGA assessment of a COVID-19 test for inclusion in the ARTG
- Conditions of supply for rapid antigen tests Q&A

PART 1: CUSTOMER DETAILS

Account No:		Date:	
Name of Company/Business/ Government Department:			

PART 2: CUSTOMER TYPE

Please select your Customer Type:

☐ **Accredited Pathology Laboratory**

- Please complete Part 3, and then sign the form

☐ A **Medical Practitioner**, or a **Paramedic**, or an **organisation, business, or institution that employs or engages a Medical Practitioner or Paramedic**, where:

- The medical practitioner or the paramedic is responsible for performing or supervising the performance of the test; and
- 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.
- Please complete Part 4, and then sign the form

☐ A **residential care** or **aged care facility**, or a **home care service provider**, which employs or engages a registered Health Practitioner (as defined by the *Therapeutic Goods Act 1989*) where:

- The Health Practitioner is responsible for performing or supervising the performance of the test; and
- 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.
- Please complete Part 4, and Part 5, and then sign the form

☐ An **organisation, business, or institution, that employs or engages a registered Health Practitioner** (as defined by the *Therapeutic Goods Act 1989*) where:

- The Health Practitioner is responsible for performing or supervising the performance of the test; and
- 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 Dental Practitioner and who requires an emergency dental procedure.
- Rapid Antigen testing is performed in the mining sector, for example, under this customer type.
- Please complete Part 4, and Part 5, and then sign the form

☐ A **department of the Commonwealth, a State, or a Territory with responsibility for health**

- Please proceed directly to signing the form

☐ A **department or other agency of the Commonwealth, a State, or a Territory, acting on the behalf of a department of the Commonwealth, that State or Territory, with responsibility for health**

- Please complete Part 6 and then sign the form

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PART 3: LABORATORY ACCREDITATION

NATA Accreditation Number:	
RCPA ID Number:	

PART 4: DETAILS OF MEDICAL PRACTITIONER, PARAMEDIC OR HEALTH PRACTITIONER PERFORMING OR SUPERVISING THE PERFORMANCE OF THE TESTING

Full Name:	
AHPRA Registration Number:	
Email:	
Phone Number:	

PART 5: TYPE OF CARE PROVIDER

☐ Aged Care Facility ☐ Residential facility (ie disability and/or rehabilitation facility) ☐ Home Care Service

PART 6: GOVERNMENT DEPARTMENTS

☐ 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.

NOTE: THE TGA REQUIRES PRACTITIONERS TO COMPLETE TRAINING BEFORE COMMENCING ANY TESTING

Please email your completed forms to: om@mdsanz.com and regulatory@ebosgroup.com.au.

SIGNATURE OF AUTHORISED PERSON

Signature:	
Full Name:	
Email:	
Phone Number:	