Checklist for application

COVID-19 Point of Care Test

Complete this form if you are applying to have a point of care test device added to the list of Ministry of Health approved SARS-CoV-2 or COVID-19 point of care tests. Please read the entire form fully and carefully.

This checklist is to be included with your application. Required criteria to be considered for approval are described on the Ministry of Health website and are requested specifically in this checklist. If proper documentation is not provided, the application will not be considered. If this is a resubmission of a previously declined application, ensure all information requested in the decline letter are addressed. Only one resubmission will be considered for 3 calendar months.

The COVID-19 Public Health Response Act 2020 which took effect from 22 April 2021 prohibits the importation and use of point of care tests in New Zealand without the authorisation of the Director General of Health.

The process to seek Director-General of Health authorisation to import/supply and/or use point of care tests is a separate and unrelated process to the Medsafe process in relation to the notification of devices to the WAND (Web-Assisted Notification of Devices) database. Notification to WAND does not indicate that a device has been assessed or approved and does not indicate that it meets any regulatory or technical requirements. Further, while notification of In Vitro Diagnostic Devices (IVDs) is encouraged, it is not a requirement of the legislation (Medicines (Database of Medical Devices) Regulations 2003). Information about WAND is available at: <http://www.medsafe.govt.nz/regulatory/DevicesNew/3WAND.asp>.

**Applicant details**

|  |  |
| --- | --- |
| Today’s date | Click or tap to enter a date. |
| Your full name:  | Click or tap here to enter text. |
| Company name (Please enter N/A if not applicable):  | Click or tap here to enter text. |
| Role in company (Please enter N/A if not applicable): | Click or tap here to enter text. |
| Your address (If company, place of business): | Click or tap here to enter text. |
| Contact number: | Click or tap here to enter text. |
| Email address: | Click or tap here to enter text. |
| Device name: | Click or tap here to enter text. |
| Device manufacturer: | Click or tap here to enter text. |

**Checklist of documentation**

**Documents have been included for stage one:**

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Required criteria | Attached | File name(s) and page numbers |
| 1. | Information for use (IFU), user manuals, or other package inserts | [ ]  | Click or tap here to enter text. |
| 2. | Packaging specifications, such as pictures, dimensions, weight, and design | [ ]  | Click or tap here to enter text. |
| 3. | Product sensitivity and specificity | [ ]   | Click or tap here to enter text. |
|  |  |  |  |
| 4. | Medical device markingsConformite Europeenne (CE) marked (manufacturer or importer affirms the goods conformity with the European health safety and environmental protection standards) or Underwriter Laboratories (UL) certification/recognised or equivalent. | [ ]  | Click or tap here to enter text. |
| 5. | Manufacturing facility standardsInternational Organizational Standard (ISO) and European standards; European Norm (EN) standards, Manufacturing Conformity, Good Manufacturing Practices, or Food and Drug Administration 21 CFR 820. | [ ]  | Click or tap here to enter text. |
| 6. | Real-time or accelerated stability study confirming the shelf-life of the device, reagents, or consumables | [ ]  | Click or tap here to enter text. |
| 7. | Certifications, authorisations, or approvals from one of the following:* 1. USA Food and Drug Administration (FDA) emergency use authorisation or approval
	2. United Kingdom Department of Health and Social Care (DHSC) approval (phase 3a validation)
	3. Medicines and Healthcare products Regulatory Agency (MHRA) approval or exceptional use authorisation
	4. WHO Emergency Use Listing for In vitro diagnostics (IVDs) Detecting SARS-CoV- 2
	5. Australia’s Therapeutics Goods Administration (TGA) approval for inclusion in the Australian Register of Therapeutic Goods (ARTG)
	6. European Commission Directorate-General for Health and Food Safety (common or mutual recognition list)
	7. Or other equivalent comparator countries and authorising environment at the discretion of the Ministry of Health.
 | [ ]  | Click or tap here to enter text. |

**Documents have been included for stage two:**

|  |  |  |  |
| --- | --- | --- | --- |
| No. | Required criteria | Attached | File name(s) and page numbers |
| 6.  | Evidence, data, or confirmation of performance against variants | [ ]  | Click or tap here to enter text. |
| 7. | Equity and considerations for Te Tiriti o Waitangi |  |  |
|  | Usability study | [ ]  | Click or tap here to enter text. |
|  | Training materials or videos demonstrating use | [ ]  | Click or tap here to enter text. |
|  | Information for Use (IFU) available in multiple languages | [ ]  | Click or tap here to enter text. |
| 8. | Data reportingProprietary application or an ability to integrate into an existing IT infrastructure or data reporting system such as ‘mycovidrecord’, via either application API or scannable QR barcode on the device. | [ ]  | Click or tap here to enter text. |
| 9. | Study or studies on clinical performance.  | [ ]  | Click or tap here to enter text. |
|  | •Entity or responsible party for conducting the study | [ ]  | Click or tap here to enter text. |
|  | •Consecutive participants with clearly defined study population with no prior knowledge of COVID-19 diagnosis (i.e., ‘unselected’). *Meeting this requirement requires detail of the method used, for example: how participants were recruited, whether they were sequentially tested, and not pre-selected on any basis such as already knowing whether they tested positive/negative. It may be necessary to consult with the manufacturer and researchers to obtain these details.* | [ ]  | Click or tap here to enter text. |
|  | •Report both sensitivity and specificity (or both can be calculated from a 2x2 table) | [ ]  | Click or tap here to enter text. |
|  | •All participants have the index and reference test | [ ]  | Click or tap here to enter text. |
|  | •Index test is the point of care test | [ ]  | Click or tap here to enter text. |
|  | •Reference test is a nucleic acid amplification test (NAAT), preferably RT-PCR | [ ]  | Click or tap here to enter text. |
|  | •Clinical performance data must meet the following thresholds: a. Overall ≥80% sensitivity and >98% specificity (recommended by WHO, ECDC, TGA, and European Commission MDCG) compared to the reference standard RT PCR or b. ≥90% sensitivity for Ct values <25 | [ ]  | Click or tap here to enter text. |