Summary for ARTG Entry: 340779  Gene Target Solutions Pty Ltd - Severe acute respiratory syndrome-associated coronavirus IVDs

ARTG entry for
Medical Device Included - IVD Class 3

Sponsor
Gene Target Solutions Pty Ltd

Postal Address
PO Box 3051, Dural, NSW, 2158 Australia

ARTG Start Date
3/08/2020

Product Category
Medical Device Class 3

Status
Active

Approval Area
IVD

Conditions
- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers
Name
Co-Diagnostics Inc

Address
2401 South Foothill Drive Suite D
Salt Lake City, UT, 84109
United States Of America

Products

1. Severe acute respiratory syndrome-associated coronavirus IVDs

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<th>Product Type</th>
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| IVD          | CT772 Severe acute respiratory syndrome-associated coronavirus IVDs | GMND Information is as follows:
|              | Code: 64747 | Name: SARS-CoV-2 nucleic acid IVD, kit, nucleic acid technique (NAT) 
|              | Definition: A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of nucleic acid from severe acute respiratory syndrome-associated coronavirus 2 (SARS-CoV-2) in a clinical specimen, using a nucleic acid technique (NAT). This test is used to aid the diagnosis of coronavirus disease (COVID-19) infection, The Logix Smart™ Coronavirus Disease 2019 (COVID-19) Test kit is an in vitro diagnostic test that uses patented CoPrimer™ technology for the qualitative detection of the RNA from SARS-CoV-2 coronavirus (COVID-19) in lower respiratory tract fluids (e.g. bronchoalveolar lavage, sputum, tracheal aspirate), and upper respiratory tract fluids (e.g. nasopharyngeal and oropharyngeal swabs).

To use this product, SARS-CoV-2 nucleic acid is first extracted, isolated, and purified from upper and lower respiratory specimens. The purified nucleic acid is then reverse transcribed into cDNA followed by PCR amplification and detection using CoPrimer technology. The Logix Smart Coronavirus Disease 2019(COVID-19) kit includes the following materials or other authorized control materials, or other authorized control materials, that are to be run as outlined in the instructions for use. All controls listed below must generate expected results for a test to be considered valid, as outlined in the instructions for use:
- Internal positive control (IPC)- RNase P (RP) control in clinical specimens: The RP primer and probe set is included in each run to test for human RNase P, which controls for specimen quality and demonstrates that nucleic acid generated by the extraction process.
- Logix Smart COVID-19 Positive Control-blend of SARS-CoV-2 synthetic templates. The positive control is used to monitor for failures of PCR reagents and reaction conditions.
- No Template (Negative) Control (NTC- Nuclease-free, molecular-grade water used to monitor non-specific amplification, cross contamination during experimental setup, and nucleic acid contamination of reagents.

Specific Conditions
Within 12 months of an approval the following information will be required to be provided to the TGA. 1. A report of any adverse events, corrective and preventative actions, and customer complaints provided in the context of the number of devices supplied since the introduction of the Device(s) to market in Australia and Worldwide. 2. Information regarding any refusals by Regulatory Authorities for the supply of the Device(s) in any other regulatory jurisdictions. 3. Further analytical and clinical evidence to support a) Analytical and clinical performance of the device b) Device stability (e.g. shelf-life stability, transport stability) 4. Instructions for use that provide updated information on the analytical and clinical performance characteristics of the device.