Australian Government

Department of Health
Therapeutic Goods Administration

TRIM Reference: E20-339105
(D20-3459991)

Hough Pharma Pty Ltd
307 Benowa Road
BENOWA VIC 4217

Email: jh@houghpharma.com

Attention: Jackson Hough

Notice under sections 41FI, 41FJ and 41FO of the *Therapeutic Goods Act 1989* of decision to include the kind of device in the ARTG and impose conditions

Device Application / Submission ID:	DV-2020-IVA-27991-1/DA-2020-07340-1
GMDN[1]:	Severe acute respiratory syndrome-associated coronavirus IVDs [CT772]
Sponsor's Reference:	1
Device Name:	**1. SARS-CoV-2 Antigen Quantitative Assay Kit (Enzyme-linked Immunoassay) 2. SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold Method)**
ARTG Entry:	345031

As a delegate of the Secretary of the Department of Health (the Secretary) for the purposes of section 41FI of the *Therapeutic Goods Act 1989* (the Act), I have made a decision to include the kind of medical device, SARS-CoV-2 Antigen Quantitative Assay Kit (Enzyme-linked Immunoassay) and SARS-CoV-2 IgM/IgG Antibody Test Kit (Colloidal Gold Method) (GMDN: Severe acute respiratory syndrome-associated coronavirus IVDs [CT772]) Class 3 (the Device) in the Australian Register of Therapeutic Goods (ARTG)[2].

Further, as a delegate of the Secretary for the purposes of section 41FO of the Act, I have decided to impose conditions on the inclusion of the Device in the ARTG.

The *conditions* imposed on both Devices are that:
Within 12 months of approval for inclusion in the ARTG the sponsor must provide to the Therapeutic Goods Administration (TGA) updated documentation and information to demonstrate ongoing evidence of the compliance of the Device(s) with the requirements of Parts 1 and 2 of Schedule 1 - Essential Principles of the Therapeutic Goods (Medical Devices) Regulations 2002, including:

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.

[1] Information as stated in the application
[2] An automatic email should have been already sent to you informing you of the decision to include the Device in the ARTG