



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

TRIM Reference: E20-53561  
(D20-475260)

**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**

<b>Device Application / Submission ID:</b>	DV-2020-IVA-06419-1/ DA-2020-02252-1
<b>GMDN<sup>1</sup>:</b>	Severe acute respiratory syndrome-associated coronavirus IVDs [CT772]
<b>Sponsor's Reference:</b>	LYHER Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)
<b>Device Name:</b>	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)
<b>ARTG Entry:</b>	To be confirmed, see next steps below

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 Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold) (GMDN: Severe acute respiratory syndrome-associated coronavirus IVDs [CT772]) Class 3 (the Device) in the Australian Register of Therapeutic Goods (ARTG)<sup>2</sup>.

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 the Device are that:**

1. The person (the sponsor) in relation to whom the Device is included in the ARTG may only supply the Device to:
  - a. laboratories that are accredited pathology laboratories; and/or
  - b. medical practitioners who are registered under a law of a State or Territory; and/or
  - c. health care professionals in residential and aged care facilities; and/or
  - d. Commonwealth, State or Territory department of health; and/or

<sup>1</sup>Information as stated in the application

<sup>2</sup>An automatic email should have been already sent to you informing you of the decision to include the Device in the ARTG