R information requested from manufacturer

in process stage complete

F follow-up amendments S

scheduled; date confirmed

Please note: these tables are updated regularly; while every attempt is made to provide current data, the most recent information might not be reflected. This table is intended only as an update on progress and does not reflect a final decision on prequalification. This table should not be used to inform procurement. Information may not yet be reflected here.

Last update: 2 July 2024.

Introduct was prequalified and a change request was submitted and accepted to add an intended use claim.

SARS-COV-2 Rapid Antigen Tests for Professions Use

Product name	Product code(s)	Manufacturer name	Dossier review	Quality Management System review	Product performance evaluation	Labelling review	Application number
STANDARD Q COVID-19 Ag Test	09COV30D, 09COV31D, 09COV32D, 09COV33D, 10COVC11	SD Biosensor, Inc.					PQDx 12369-117-00
Artron COVID-19 Antigen Test	A03-50-422W	Artron Laboratories Inc.	R				PQDx 12360-168-00