



# NAMIBIA MEDICINES REGULATORY COUNCIL

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## PUBLIC NOTICE 002/2022

### APPROVED ANTIGEN RAPID DIAGNOSTIC KITS FOR USE IN NAMIBIA

The Namibia Medicines Regulatory Council (NMRC) hereby lists Antigen Rapid Diagnostic Test Kits (Ag-RDT) that have met all regulatory requirements and have therefore received approval for use under defined conditions.

S/ N	APPROVED NAME OF MEDICAL DEVICE(S)	MANUFACTURER AND SITE ADDRESS
1.	SD Biosensor Standard Q COVID-19 Antigen Kit	SD Biosensor, Inc 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheogju-si, Chungcheongbuk-do 28161, KOREA
2.	PANBIO™ COVID-19 Antigen Kit	Abbott Rapid Diagnostic Jena GmbH, Orlaweg 1, 07743 Jena, Germany
3.	Green Spring SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Shenzhen Lvshiyuan Biotechnology Co., Ltd, China
4.	Lumira Dx SARS-CoV-2 Antigen Test	LumiraDx UK Ltd Dumyat Business Park, United Kingdom
5.	SARS-COV-2 Rapid Antigen Test (Roche)	SD Biosensor, Inc 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheogju-si, Chungcheongbuk-do 28161, KOREA
6.	VivaDiag Sars-Cov-2-Ag Rapid Test Kit	Vivacheck Biotech (Hangzhou) Co. Ltd Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China
7.	On-Site® COVID-19 Ag Rapid Test	CTK Biotech Inc. A/S 13855 Stowe Dr, Poway CA 92064 USA

8.	Flowflex SARS- Cov-2-Ag Rapid Test	Acon Biotech (Hangzhou) Co. Ltd. No.210 Zhenzhong Road, West Lake District, 310030 Hangzhou, PEOPLE REPUBLIC OF CHINA
9.	COVID-19 Ag Sealing Tube Test Strip (Colloidal gold)	Amazing Biotech (Shanghai) Co., Ltd. 3 / F, Building 1, No. 48-52 Gucui Road, Xinchang Town, Pudong New Area, Shanghai, China. 201314

**The following are the conditions for use of the approved test kits:**

1. The rapid test kits should **ONLY** be supplied to and used in health facilities (as defined in the Health Facility Act No 36 of 1994) or institutions where certified medical personnel are present to perform the test. The supplier should at all times provide the NMRC with the list of recipients (end-users) of the test kits.
2. It is the responsibility of the supplier to ensure that the medical personnel to be performing the tests have received appropriate training on specimen collection, Ag-RDT testing (MoHSS algorithm) and biosafety measures. Therefore, only certified users are permitted to perform the tests.
3. Medical personnel conducting tests should adhere to the most recent Ministry of Health and Social Services Guidance on Rapid Diagnostic Testing for Covid-19 Response.
4. Medical Personnel (end-users of the test kits) **MUST** report all their test results to the Ministry of Health and Social Services.
5. Medical personnel (end-users of the test kits) should provide the NMRC with an activity report after one month of use including experiences with the use of the kits, operational or diagnostic challenges or successes.
6. End-users, distributors and/or manufacturers must report any adverse event or product problem.
7. End-users, distributors and/or manufacturers must report suspected falsified product or suspected unapproved devices to NMRC.
8. Authorization for any Ag-RDT may be revoked if the condition(s) under which it was issued are not met or if new evidence that do not support use emerges.

Yours sincerely,  
  
 FRANSINA NAMBAHU  
 REGISTRAR OF MEDICINES