

Appendix C COVID-19 Home Testing using Rapid Antigen Tests (RATs)



भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार
Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

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COVID-19 Home Testing using Rapid Antigen Tests (RATs)

Please Note:

- Acceptance criteria:
 - For already approved RAT kits with alternate sample:
Concordance between already approved RAT and home/self test: 95% and above
 - For new RAT kits as home/self test:
Sensitivity: 50% and above; Specificity: 95% and above
- Below listed kits have been validated with the mentioned batch number only. Responsibility for batch-to-batch consistency does not lie with ICMR.
- US-FDA approved Antigen based COVID-19 Home/Self tests are exempted from ICMR validation.

Till date, 17 Rapid Ag based Home / Self Test Kits have been validated and the following are found to be satisfactory

S. No.	Name of company	Name of the kit	Lot no. / Batch no.	Test Sample	Guidance Documents
1.	Mylab Discovery Solutions Ltd., Pune (Maharashtra), India	CoviSelf™ (PathoCatch) COVID-19 OTC Antigen LF device	AG00003-A-0421001E AG00003-A-0421002E AG00003-A-0421003E	Nasal swab	A. IFU: http://coviself.com/ifu/ B. Video Link for demonstration video along with illustrated Video In English and Hindi http://coviself.com/video/
2.	Abbott Rapid Diagnostics Division, Chicago (Alere Medical Pvt. Ltd., Gurugram)	PanBio COVID-19 Antigen Rapid Test Device	41ADF315A 41ADF316A 41ADF317A	Nasal swab	A. IFU- Hindi ; English B. Link for demonstration video - Link for Demonstration Video
3.	Meril Diagnostics Pvt. Ltd., Vapi (Gujarat), India	CoviFind COVID-19 Rapid Ag Self Test	MRDLF130221	Nasal swab	A. IFU https://www.merillife.com/assets/pdfs/medical-devices/Covifind-IFU.pdf B. Video link for demonstration https://youtu.be/dA_A0cZ_4M
4.	Angstrom Biotech Pvt. Ltd.	Angcard COVID-19 Home test kit	BCOVN01 BCOVN02 BCOVN03	Saliva	A. IFU https://drive.google.com/file/d/19IiCi8gjO32m08DkyabrZM2lmg7Xn0t/view?usp=sharing B. Video link for demonstration: https://www.youtube.com/channel/UCQ0pG0I-GH-qqi6SVcrKlkg
S. No.	Name of company	Name of the kit	Lot no. / Batch no.	Test Sample	Guidance Documents



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5.	Healgen Scientific Limited, USA (Siemens Healthcare Pvt. Ltd., Gurugram)	CliniTest COVID-19 Antigen Self Test	2104730	Nasal Swab	A. IFU- English ; Hindi B. Video link for demonstration https://www.siemens-healthineers.com/en-in/clinitest-rapid-covid-19-self-test
6.	S. D. Biosensor Healthcare Pvt. Ltd., Gurugram (Haryana), India	ULTRA Covi-Catch™ SARS-CoV-2 Home Test	T070001/RK07-0-01 E070002	Nasal swab	A. IFU- English ; Hindi B. Video link for demonstration English: https://sdbiosensor.co.in/english-video-5.php Hindi: https://sdbiosensor.co.in/hindi-video-3.php
7.	Nulife Care, Noida (Uttar Pradesh), India	AbCheck Rapid Antigen Self Test - Nasal	COV/AG/RND/21/06/01/B3	Nasal swab	A. IFU- English ; Hindi B. Video link for demonstration Nulife Care
8.	SD Biosensor, Korea (Supplied by Roche Diagnostics)	COVID-19 AtHome Test Kit (Nasal)	QC03810411 QC03810471 QC03810521	Nasal swab	A. IFU- English ; Hindi
9.	Genes2Me Pvt. Ltd., India	CoviEasy COVID-19 Rapid Ag Self Test kit	G2M550001	Nasal swab	A. IFU- English ; Hindi B. Video link for demonstration: bit.ly/3lQYllg
10.	Premier Medical Corporation, Valsad (Gujarat), India	SureStatus COVID-19 Ag Card test (Home Test) kit	106F0121S	Nasal swab	A. IFU- English ; Hindi B. Video link for demonstration: https://youtu.be/ilv_Z17dRUs
11.	NeoDx Biotech Labs Pvt. Ltd., Bengaluru (Karnataka), India	NeoCheck - Covid-19 Rapid Antigen Self test Kit	COV1070022 COV1070027 COV1070028	Nasal swab	A. IFU- English ; Hindi B. Video link for demonstration: https://youtu.be/j1XEI5oZjkk

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Rapid Ag based Home / Self Test Kits, NOT approved by ICMR

S. No	Name of Company	Name of Kit	India/ Other countries	Name of the supplier
1.	Trivitron Healthcare Pvt. Ltd.	MyCoviTest Self Test Kit	India	Trivitron Healthcare Pvt. Ltd.
2.	Oscar Medicare Pvt. Ltd., Delhi	OSKIT Corona Ag Home Test	India	Oscar Medicare Pvt. Ltd.
3.	Oscar Medicare Pvt. Ltd., Haridwar (Uttarakhand)	OSKIT Corona Ag Home Test	India	Oscar Medicare Pvt. Ltd.
4.	Pathkits Healthcare Pvt. Ltd.	COVIatHome	India	Pathkits Healthcare Pvt. Ltd.
5.	Labcare Diagnostics (India) Pvt. Ltd.	Accucare COVID-19 Antigen Saliva Rapid Test kit	India	Labcare Diagnostics (India) Pvt. Ltd.
6.	DNA Xperts Pvt. Ltd.	Xperts Covid Self Check COVID-19 Rapid Ag kit	India	DNA Xperts Pvt. Ltd.