



Date:05.08.2021

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, 6 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) COV ID-19 OTC Antigen LF device	AG00003-A-0421001E AG00003-A-0421002E AG00003-A-0421003E	Nasal swab	A.Link For IFU in English and Hindi - 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	Link for IFU, Hindi English Link for Demonstration Video
3.	Meril Diagnostics Pvt. Ltd., Vapi (Gujarat), India	CoviFind COVID-19 Rapid Ag Self Test	MRDLF13022 1	Nasal swab	A. Link For IFU https://www.merillife.com/assets/pdfs/medical-devices/Covifind-IFU.pdf B. Video link for demonstration https://youtu.be/dA_A0cZ_4M



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कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Annexure I

Rapid Ag based Home / Self Test Kits kits validated, 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.