



Date:06.01.2022

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, 12 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/191liCi8gjO32m08DkyabrZM2lmg7Xn0t/view?usp=sharing B. Video link for demonstration: https://www.youtube.com/channel/UCQ0pGOI-GH-qqi6SVcrKlkg |



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

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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 |



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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. |